THERAPEUTIC PRODUCTS COMPLIANCE GUIDE

This guide does not have any official legal status. It is a reference document and appropriate official documents should be consulted.

Ce document est également disponible en français.

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List of amendments to the TPCG

Amendement #	Date [aa/mm/jj]	Commentaires
1	1998-05-26	1- Additions to Schedule F part 1 : under letters M and N, several entries were missing as well as Penicillamine. 2- Under Schedule III (CDSA), addition of flunitrazepam and GHB, deletion of Flunitrazepam from Shcedule IV (CDSA). 3- Addition of acceptable sources for Sulphur. 4- Correction to Schedule F for Nicotine, Astemizol and Terfenadine 5- Precision under Chaparral 6- Modification to Echemidine
2	1998-08-11	1- Modification to figure 4 2- Additions / deletions / corrections to Schedule F (Sectic 1.3.3) 3- Additon of a **Note** to Cantharides, Cantharidin and the preparations (section 1.5) 4- Addition of an acceptables source for Molybdenu (Section 1.6.1) 5- Additional information on Mineral Supplements (Sectic 1.6.1) 6- Additional information on Vitamin Supplements (Sectic 1.6.2)

1

Introduction

The **Therapeutic Products Compliance Guide** (TPCG) is a reference document to aid in assessing the compliance status of products that fall within the scope of the Interim DIN Enforcement Directive of the Therapeutic Products Programme. The TPCG applies to all human drugs in dosage form (veterinary drugs are not covered).

The TPCG is intended primarily for use by regulatory officials and evaluators of the Therapeutic Products Programme. Other potential users include regulatory officials of Revenue Canada (Customs) and of the Canadian Food Inspection Agency. This guide may also be used by industry and other stakeholders to help assess compliance with DIN/GP requirements of the *Food and Drug Regulations*. The expected outcomes of using this guide are improved efficiency and uniformity in carrying out the Interim DIN Enforcement Directive and improved compliance of products.

The Interim DIN Enforcement Directive gives direction to inspection personnel on available enforcement measures when a non-compliant product is encountered. For the purpose of enforcement, the products of interest are separated into two categories: **products subject to special measures** and **products not subject to special measures**.

For **products subject to special measures** lacking a valid DIN/GP, this guide may be used to determine if such products satisfy one of the criteria identified in the Interim DIN Enforcement Directive. It provides the information necessary to evaluate whether a product under review satisfies any of the criteria specified in the Interim DIN Enforcement Directive. The guide, therefore, identifies substances and claims; synonyms and regulatory references, as appropriate; and concentration of substances or dosage forms and other information pertaining to the assessment criteria.

The lists in section 1 of the TPCG correspond with the criteria established under section 5.a) of the Interim DIN Enforcement Directive for **products subject to special measures**. In addition, section 1 includes information on the mineral and vitamin supplements specifically covered under **products subject to special measures,** to help in assessing compliance.

The list in section 2 relates to **products not subject to special measures**. It covers substances considered a drug, regardless of the type of representation made regarding the product.

This list (section 2) is intended to identify substances considered to be a drug as defined by the Food and Drugs Act. It is important to note that the Act establishes

what a drug "includes", but not what a drug "is". It also distinguishes drugs on the basic of the purpose for which the substance is manufactured, sold or represented.

The major factors used in determining whether a product is to be considered a drug are: the pharmacological activity of the ingredients; the purpose for which the product is intended; and the representations made regarding its use, including directions for use. Other factors, such as precise dosage form, design features of a product (e.g. a patch delivery system which is intended as a drug by design), may be considered in the determination of a product status. For example, a product containing a substance with known pharmacological activity such as acetaminophen, will be considered a drug even in the absence of a medicinal claim. Conversely, a product represented for medicinal purposes would be considered a drug, requiring the safety and efficacy of the active substances be established. Both these products would require a valid DIN.

It is not the intent to include in section 2, a comprehensive listing of information pertaining to the three major factors used in determining the drug status of a product. This section will be limited to a few substances that have been found in products considered to be drugs in the Canadian marketplace, and for which the safety and efficacy have not been established.

The Therapeutic Products Compliance Guide will be updated when legislative amendments are promulgated, and when new or revised health hazard decisions are made.

Instructions for status assessment

When using the TPCG to assess the status of a substance or the legality of a labelling claim, users should first search the index to identify all the relevant information on the subject.

Several approaches can be used to assess the status of a product in relation to the Interim DIN Enforcement Directive. A suggested approach is to answer the following series of questions (See also Figures 1 to 5).

1. **Does the product have a DIN/GP?**

   If yes, proceed to question 2.
   If no, proceed to question 3.

2. **If the product has a DIN/GP, is it valid?**

   If yes, no action required.
   If the DIN/GP is not valid, the product is not in compliance (refer to Interim DIN Enforcement Directive).

3. **If the product has no DIN/GP, determine whether the product is within the scope of the Interim DIN Enforcement Directive?**

   If the product is not within the scope of the directive, no further action is warranted since the Interim DIN Enforcement Directive does not apply.

   If the product is within the scope of the directive, determine whether it is a product subjects to special measures or a product not subjects to special measures.

   If it is a product subjects to special measures, proceed to question 4.

   If it is a product not subjects to special measures, proceed to question 5.

4. **Products subject to special measures with no DIN**:

   Check labelling information against each assessment criteria.

   If the product does not meet one of the 5 criteria outlined in section 5. a) of the Interim DIN Enforcement Directive, provide the information on DIN requirements

in order to obtain voluntary compliance. If the product satisfies one of the criteria outlined in section 5. a) of the Interim DIN Enforcement Directive, appropriate enforcement measures should be taken to control its distribution.

5. **Products not subject to special measures with no DIN:**

Refer to section 2.1, and statements in the introduction.

If a DIN/GP is required, take appropriate enforcement measures as specified in the Interim DIN Enforcement Directive to control its distribution

6. **Where the status of a product is not known, consult other Therapeutic Product Programme (TPP) publication; most are available on the TPP website. For more details refere to Drug Status Evaluation Request Standard Operating.**

7. **Where the status of a product remain unknown, initiate a status request to the TPCG Coordinator.**

The TPCG Coordinator is a member of the Office of Compliance and Regional Liaison, Therapeuthic Products Programme (Ottawa).

Fig. 4 A Suggested Process for Status Assessment

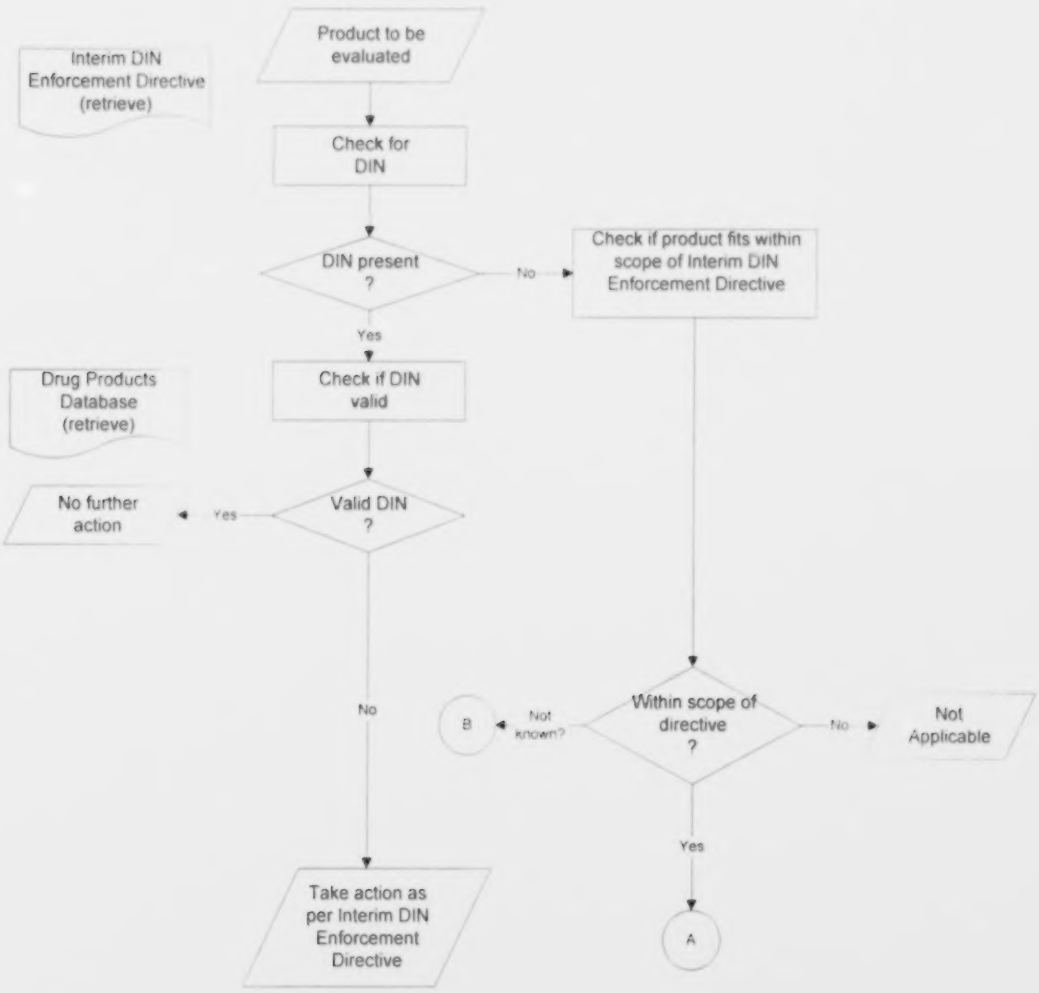


Fig 2
Continuation of Figure 1
(Connector 'A')

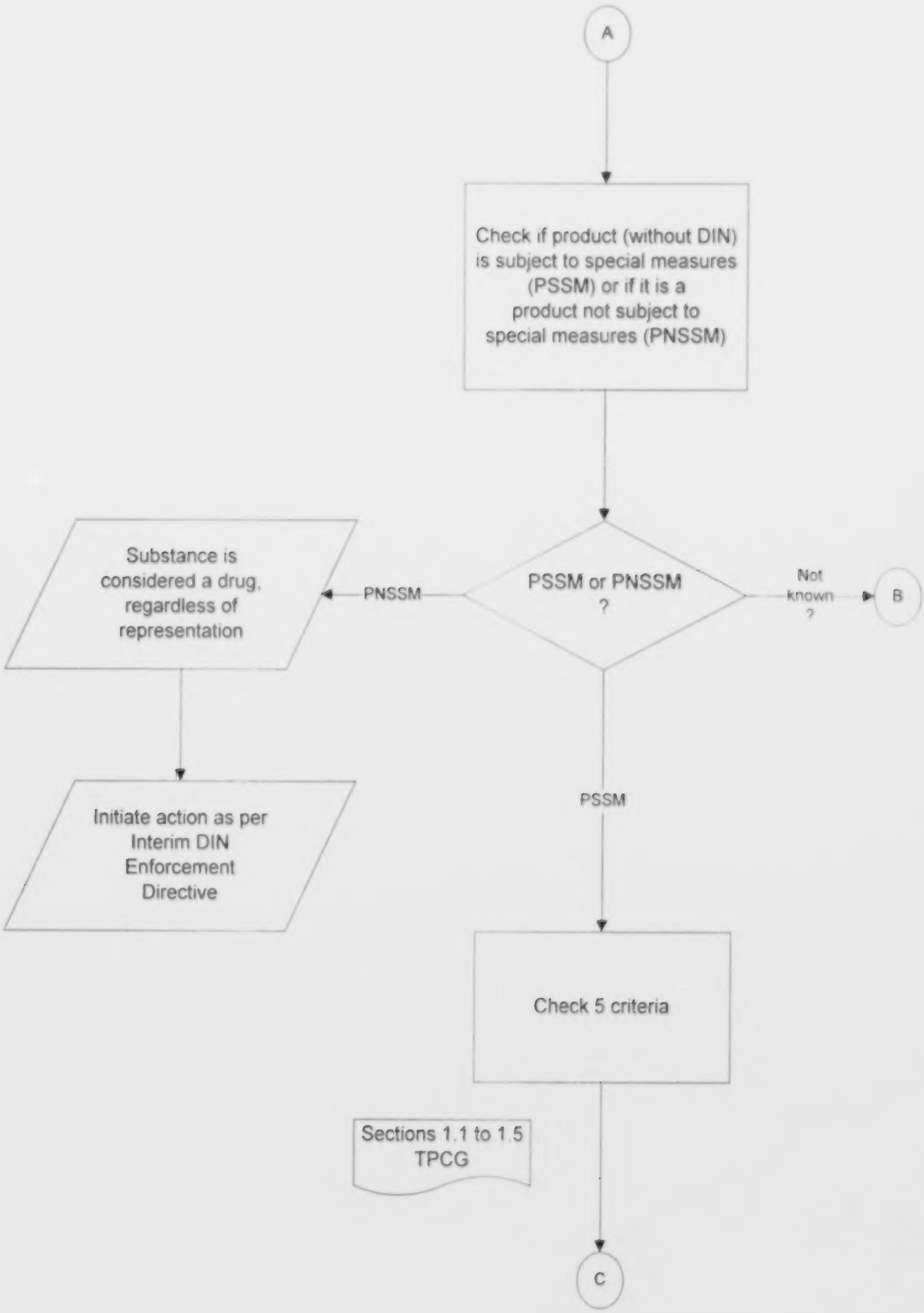
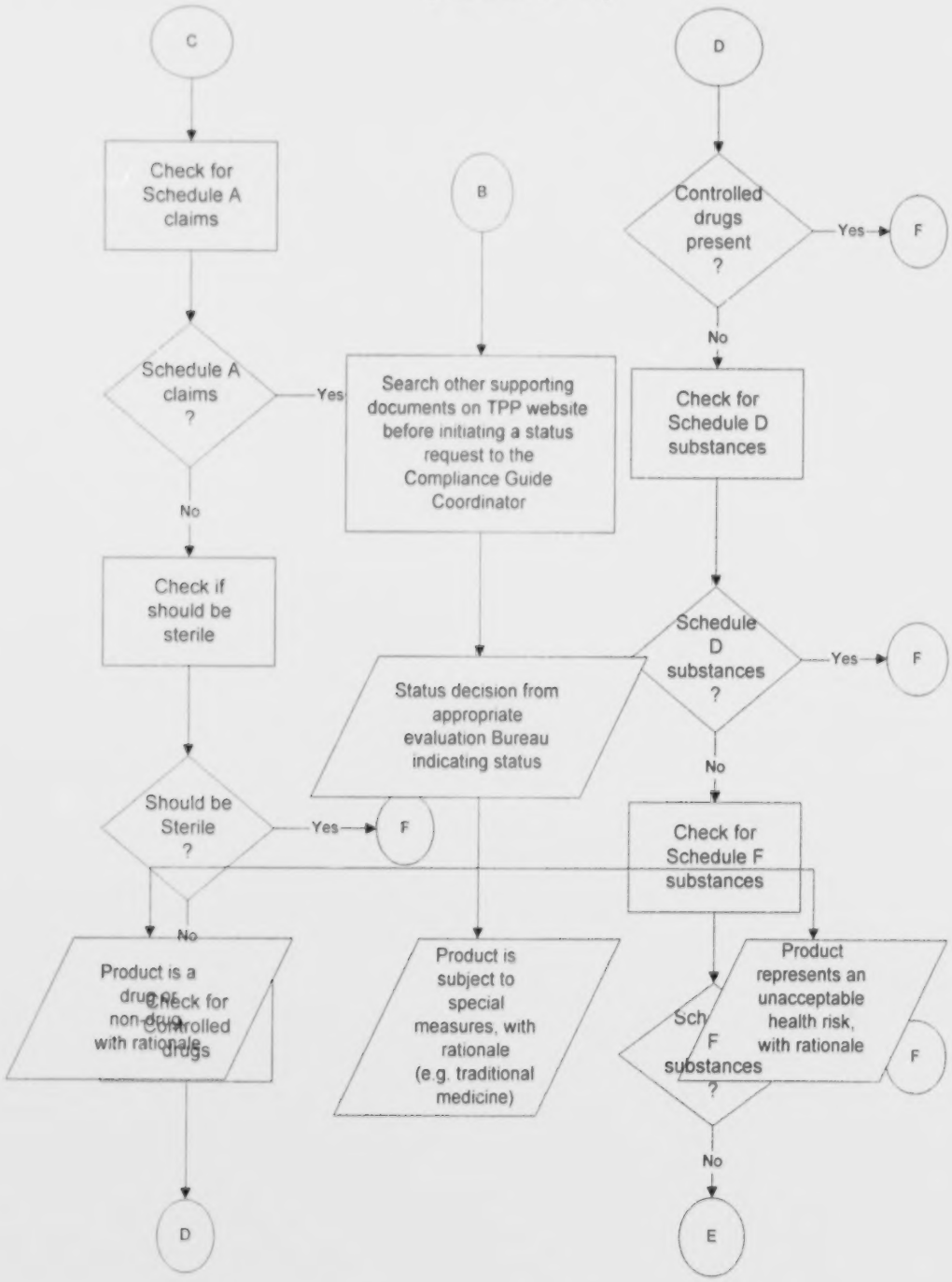

A
Check if product (without DIN) is subject to special measures (PSSM) or if it is a product not subject to special measures (PNSSM)
PSSM or PNSSM ?
PNSSM
Substance is considered a drug, regardless of representation
Initiate action as per Interim DIN Enforcement Directive
Not known ?
B
PSSM
Check 5 criteria
Sections 1.1 to 1.5 TPCG
C

Fig. 3
Continuation of Figure 2
(Connector 'C')

Fig. 5
Instructions for Status Assessment
Continuation of Fig. 1, 2, & 4
(Connector 'B')



Acronyms / Definitions

Acronyms

CDSA :
Controlled Drugs and Substances Act

DIN :
Drug Identification Number

FDA :
Food and Drugs Act

FDR :
Food and Drug Regulations

GP:
General Public

PNSSM :
Products not subject to special measures

PSSM :
Products subject to special measures

TPCG :
Therapeutic Products Compliance Guide

Definitions

Class monograph :
Means a document prepared by the Department of Health that
(a) lists the types and strengths of medicinal ingredients that may be contained in drugs of a specified class; and
(b) sets out labelling and other requirements that apply to those drugs.

Drug :

The definition of "drug" in the Food and Drugs Act includes any substance or mixture of substances manufactured, sold or represented for use in

(a) the diagnosis, treatment, mitigation or prevention of a disease, disorder, abnormal physical state, or its symptoms, in human beings or animals,
(b) restoring, correcting or modifying organic functions in human being or animals, or
(c) disinfection in premises in which food is manufactured, prepared or kept.

Mineral supplements :
Mineral supplements are those that meet the requirements of a class monograph entitled "Mineral Supplements" or "Dietary Mineral Supplements", as the case may be.

Products subject to special measures:
Refer to traditional medicines (i.e. traditional herbal medicines as well as traditional medicines such as Chinese, ayurvedic (East Indian) and aboriginal (North American) medicines), homeopathic preparations and vitamin and mineral supplements, for human use, when in dosage form and for which prescriptions are not required.

Therapeutic products:
Includes pharmaceuticals and biologicals, herbals, homeopathics, vitamins and minerals, disinfectants, and medical devices.

Traditional Medicines (TM) :
Drugs that :

(a) contain a plant, mineral or animal substance in respect of which therapeutic activity or disease prevention activity is claimed, including traditional herbal medicines, traditional Chinese medicines, ayurvedic (East Indian) medicines, and traditional aboriginal (North American) medicines, and
(b) the medical use of which is based solely on historical and ethnological evidence from references relating to a medical system other than one based on conventional scientific standards.

Vitamin supplements :
Vitamin supplements are those that meet the requirements of class monograph entitled "Vitamin Supplements" or "Dietary Vitamin Supplements ", as the case may be.

Section 1. Products Subject to Special Measures (PSSM)

1.1 Schedule A claims

The following is a list of the diseases, disorders or abnormal physical states referred to in Schedule A of the Food and Drugs Act.

Alcoholism
Alopecia
Anxiety states
Appendicitis
Arteriosclerosis
Arthritis
Asthma
Bladder disease
Cancer
Convulsions
Depression
Diabetes
Disease of the prostate
Disorder of menstrual flow
Dysentery
Edematous state
Epilepsy
Gall Bladder disease
Gangrene
Glaucoma
Gout
Heart disease
Hernia
Hypertension
Hypotension
Impetigo
Kidney disease
Leukemia
Liver disease
Nausea and vomiting of pregnancy
Obesity
Pleurisy
Rheumatic fever
Septicemia
Sexual impotence
Thrombotic and Embolic disorders
Thyroid disease
Tumor
Ulcer of the gastro-intestinal tract
Venereal disease

Claims synonymous with Schedule A diseases/disorders

This section lists some frequently encountered claims that would be considered synonymous with the diseases, disorders or abnormal physical states referred to in Schedule A of the *Food and Drugs Act*.

ALCOHOLISM

Synonymous claims:
Liquor or drinking habit.

ANXIETY STATES

Synonymous claims:
Apprehension, worry, concern, fear and tension.

Note: An acceptable drug may be promoted for the treatment of edgy nerves, nervous, headaches nervousness, edginess, jitteriness, insomnia or sleeplessness.

ARTERIOSCLEROSIS

Synonymous claims:
Coronary artery disease, arteriosclerotic ulcer, hardening of the arteries, circulatory troubles.

ARTHRITIS

Note: Suitably medicated products may be represented as aids in alleviating the pain of arthritis or as being for the relief of arthritic pain.

BLADDER DISEASE

Synonymous claims:
Inflammation of the bladder, bladder trouble

CONVULSIONS

Synonymous claims:
Anticonvulsant.

DEPRESSION
Synonymous claims:
Feelings of sadness, dejection, hopelessness, unhappiness, or apathy; phobic attitude, neurosis.

DISEASE OF THE PROSTATE

Synonymous claims:
Prostatism, urinary incontinence, prostatic problems.

DISORDER OF THE MENSTRUAL FLOW

Synonymous claims:
Amenorrhea, delayed menstruation, menstrual irregularity.

Note : Suitable products may be advertised as being helpful to relieve the pain associated with menstruation, premenstrual tension, symptoms associated with menopause, and premenstrual syndromes.

EDEMATOUS STATE

Synonymous claims:
Bloating, water retention, puffiness, swelling, pitting, dropsy.

Note : Appropriately medicated product may be represented for temporary water retention, bloating, swelling, and/or full feeling associated with the premenstrual and menstrual periods.

EPILEPSY

Synonymous claims:
Anticonvulsant, antiepileptic, petit mal or grand mal seizures.

GALL BLADDER DISEASE

Synonymous claims:
Gall stones, biliary dyskinesia, gall bladder troubles, biliary tract antispasmodic.

GOUT

Synonymous claims:

Gouty arthritis, gouty disease.

HYPERTENSION

Synonymous claims:
Antihypertensive agent, high blood pressure, poor circulation.

HYPOTENSION

Synonymous claims:
Hypertensive agent, low blood pressure, poor circulation, diminished tension, sluggish blood.

IMPETIGO

Note: Acceptable drugs may be promoted as providing relief from, or treatment for minor skin infections.

KIDNEY DISEASE

Synonymous claims:
Kidney troubles, flush out the kidney.

Note: Sufficiently medicated drugs may claim to be mild diuretics or to increase the flow of urine.

LIVER DISEASE

Synonymous claims:
Jaundice, hepatitis, cirrhosis, inactive or congested liver, liver troubles.

NAUSEA AND VOMITING DUE TO PREGNANCY

Synonymous claims:
Morning sickness, drowsiness, vertigo, dizziness occurring during pregnancy.

Note: Anti-emetic agents may be represented for relief of motion sickness, but no suggestion for use during pregnancy may be made.

OBESITY

Synonymous claims:
Anti-obesity agent.

Note: The promotion of over the counter (OTC) drugs to assist in weight loss is acceptable under the following conditions :

a) The drug is marketed in conjunction with a reducing plan, program, diet, or course that promotes a reduced intake of dietary calories with a possible increase in physical activity.
b) It should be clearly indicated to the consumer that it is the modification of dietary intake and physical activity that will be the instrument of weight loss.
c) The purpose of the drug in the weight-loss plan should be clearly identified as being an aid in curbing hunger and in improving program compliance.

SEPTICEMIA

Synonymous claims:
Systemic anti-infective, blood purifiers.

SEXUAL IMPOTENCE

Synonymous claims:
Frigidity, decreasing virility or manly power, aphrodisiac.

THYROID DISEASE

Synonymous claims:
Thyroid problems, hypothyroidism, hyperthyroidism, goitre.

ULCER OF THE GASTROINTESTINAL TRACT

Synonymous claims:
Peptic ulcer, ulcerative colitis, duodenal ulcer.

Note: Products that are appropriately medicated may be promoted for hyperacidity, excess acid or gas, heartburn, upset stomach or acid indigestion, or hypermobility of the gastrointestinal tract.

VENEREAL DISEASE

Note: Acquired immune deficiency syndrome (AIDS) is considered to fall under the scope of Schedule A through this listing.

1.2 Sterility requirements

The lists in this section are to give guidance on the information to consider when determining whether sterility is a requirement for a drug preparation. Drug preparation for ophthalmic and parenteral use are required to be sterile. Routes of administration include the following :

1) Ophthalmic use:

artificial tears for eyes, contact lens solutions

2) Parenteral use:

epidural
hypodermic (injectable)
Intra-amniotic
intra-arterial
intra-articular
intracardiac
intracerebral
intracranial
intracutaneous
intradermal
intradiscal
intramuscular (IM)
intraperitoneal
intrapleural
intraspinal
intrathecal
intravascular
intravenous (IV)
irrigating solutions
percutaneous
peritoneal dialysis fluids
subcutaneous (SC)

Note: The above listings are not exhaustive.

Regulatory authority: FDR, section C.01.065

1.3 Scheduled substances

1.3.1 Substances listed in Schedules I to IV of the *Controlled Drugs and Substances Act*

SCHEDULE I

1. Opium Poppy (Papaver somniferum), its preparations, derivatives, alkaloids and salts, including:

(1) Opium
(2) Codeine (methylmorphine)
(3) Morphine (7,8–didehydro–4,5–epoxy–17–methylmorphinan–3,6–diol)
(4) Thebaine (paramorphine), and the salts, derivatives and salts of derivatives of substances set out in subitems (1) to (4), including:
(5) Acetorphine (acetyletorphine)
(6) Acetyldihydrocodeine(4,5–epoxy–3–methoxy–17–methylmorphinan–6–ol acetate)
(7) Benzylmorphine(7,8–didehydro–4,5–epoxy–17–methyl–3–(phenylmethoxy)morphinan–6–ol)
(8) Codoxime (dihydrocodeinone O–(carboxymethyl)oxime)
(9) Desomorphine (dihydrodeoxymorphine)
(10) Diacetylmorphine (heroin)
(11) Dihydrocodeine (4,5–epoxy–3–methoxy–17–methylmorphinan–6–ol)
(12) Dihydromorphine (4,5–epoxy–17–methylmorphinan–3,6–diol)
(13) Ethylmorphine(7,8–didehydro–4,5–epoxy–3–ethoxy–17–methyl-morphinan–6–ol)
(14) Etorphine(tetrahydro–7α–(1–hydroxy–1–methylbutyl)–6,14–endo–ethenooripavine)
(15) Hydrocodone (dihydrocodeinone)
(16) Hydromorphinol (dihydro–14–hydroxymorphine)
(17) Hydromorphone (dihydromorphinone)
(18) Methyldesorphine (Δ6–deoxy–6–methylmorphine)
(19) Methyldihydromorphine (dihydro–6–methylmorphine)
(20) Metopon (dihydromethylmorphinone)
(21) Morphine–N–oxide (morphine oxide)
(22) Myrophine (benzylmorphine myristate)
(23) Nalorphine (N–allylnormorphine)

(24) Nicocodine (6–nicotinylcodeine)
(25) Nicomorphine (dinicotinylmorphine)
(26) Norcodeine (N–desmethylcodeine)
(27) Normorphine (N–desmethylmorphine)
(28) Oxycodone (dihydrohydroxycodeinone)
(29) Oxymorphone (dihydrohydroxymorphinone)
(30) Pholcodine (3–[2–(4–morpholinyl)ethyl]morphine)
(31) Thebacon (acetyldihydrocodeinone)

But not including

(32) Apomorphine(5,6,6a,7–tetrahydro–6–methyl–4H–dibenzo[de,g]quinoline–10,11–diol)
(33) Cyprenorphine(N–(cyclopropylmethyl)–6,7,8,14–tet-rahydro–7α–(1–hydroxy–1–methylethyl)–6,14–endo- –ethenonororipavine)
(34) Naloxone (4,5α–epoxy–3,14–dihydroxy–17–(2–propenyl)morphinan–6–one)
(35) Narcotine(6,7–dimethoxy–3–(5,6,7,8–tetrahydro–4—methoxy–6–methyl–1,3–dioxolos[4,5–g]isoquinolin- –5–yl)–1(3H)–isobenzofuranone)
(36) Papaverine (1–[(3,4–dimethoxyphenyl)methyl]–6,7–dimethoxyisoquinoline)
(37) Poppy seed

2. Coca (Erythroxylon), its preparations, derivatives, alkaloids and salts, including:

(1) Coca leaves
(2) Cocaine (benzoylmethylecgonine)
(3) Ecgonine (3–hydroxy–2–tropane carboxylic acid)

3. Phenylpiperidines, their intermediates, salts, derivatives and analogues and salts of intermediates, derivatives and analogues, including:

(1) Allylprodine (3–allyl–1–methyl–4–phenyl–4–piperidinol propionate)
(2) Alphameprodine (α–3–ethyl–1–methyl–4–phenyl–4–piperidinol propionate)
(3) Alphaprodine (α–1,3–dimethyl–4–phenyl–4–piperidinol propionate)
(4) Anileridine(ethyl1–[2–(p–aminophenyl)ethyl]–4–phenylpiperidine–4–carboxylate)
(5) Betameprodine (β–3–ethyl–1–methyl–4–phenyl–4–piperidinol propionate)
(6) Betaprodine (β–1,3–dimethyl–4–phenyl–4–piperidinol propionate)
(7) Benzethidine (ethyl 1–(2–benzyloxyethyl)–4–phenylpiperidine–4–carboxylate)
(8) Diphenoxylate(ethyl1–(3–cyano–3,3–diphenylpropyl)–4–phenylpiperidine–4–carboxylate)
(9) Difenoxin(1–(3–cyano–3,3–diphenylpropyl)–4–phenylpiperidine–4–carboxylate)

(10) Etoxeridine(ethyl1–[2–(2–hydroxyethoxy) ethyl]–4–phenylpiperidine–4–carboxylate)
(11) Furethidin(ethyl1–(2–tetrahydrofurfuryloxyethyl)–4–phenylpiperidine–4–carboxylate)
(12) Hydroxypethidine(ethyl4–(m–hydroxyphenyl)–1–methylpiperidine–4–carboxylate)
(13) Ketobemidone (1–[4–(m–hydroxyphenyl)–1–methyl–4–piperidyl]–1–propanone)
(14) Methylphenylisonipecotonitrile (4–cyano–1–methyl–4–phenylpiperidine)
(15) Morpheridine (ethyl 1–(2–morpholinoethyl)–4–phenylpiperidine–4–carboxylate)
(16) Norpethidine (ethyl 4–phenylpiperidine–4–carboxylate)
(17) Pethidine (ethyl 1–methyl–4–phenylpiperidine–4–carboxylate)
(18) Phenoperidine(ethyl1–(3–hydroxy–3–phenylpropyl)–4–phenylpiperidine–4–carboxylate)

(19) Piminodine(ethyl1–[3–(phenylamino)propyl]–4–phenylpiperidine–4–carboxylate)
(20) Properidine (isopropyl 1–methyl–4–phenylpiperidine–4–carboxylate)
(21) Trimeperidine (1,2,5–trimethyl–4–phenyl–4–piperidinol propionate)
(22) Pethidine Intermediate C (1–methyl–4–phenylpiperidine–4–carboxylate)

But not including

(23) Carbamethidine(ethyl1–(2–hydroxy–2–phenyl–ethyl)–4–phenylpiperidine–4–carboxylate)
(24) Oxpheneridine(ethyl1–(2–hydroxy–2,2–phenyl ethyl)–4–phenylpiperidine–4–carboxylate)

4. Phenazepines, their salts, derivatives and salts of derivatives including:

(1) Proheptazine (hexahydro–1,3–dimethyl–4–phenyl–1H–azepin–4–ol propionate)

But not including

(2) Ethoheptazine (ethyl hexahydro–1–methyl–4–phenyl–azepine–4–carboxylate)
(3) Metethoheptazine(ethylhexahydro–1,3–dimethyl–4–phenylazepine–4–carboxylate)
(4) Metheptazine (ethyl hexahydro–1,2–dimethyl–4–phenylazepine–4–carboxylate)

5. Amidones, their intermediates, salts, derivatives and salts of intermediates and derivatives including:

(1) Dimethylaminodiphenylbutanonitrile(4–cyano–2–dimethylamino–4,4–diphenylbutane)
(2) Dipipanone (4,4–diphenyl–6–piperidino–3–heptanone)
(3) Isomethadone (6–dimethylamino–5–methyl–4,4–diphenyl–3–hexanone)
(4) Methadone (6–dimethylamino–4,4–diphenyl–3–heptanone)
(5) Normethadone (6–dimethylamino–4,4–diphenyl–3–hexanone)
(6) Norpipanone (4,4–diphenyl–6–piperidino–3–hexanone)
(7) Phenadoxone (6–morpholino–4,4–diphenyl–3–heptanone

6. Methadols, their salts, derivatives and salts of derivatives including:

(1) Acetylmethadol (6–dimethylamino–4,4–diphenyl–3–heptanyl acetate)
(2) Alphacetylmethadol (α–6–dimethylamino–4,4–diphenyl–3–heptanol acetate)
(3) Alphamethadol (α–6–dimethylamino–4,4–diphenyl–3–heptanol)
(4) Betacetylmethadol (β–6–dimethylamino–4,4–diphenyl–3–heptanol acetate)
(5) Betamethadol (β–6–dimethylamino–4,4–diphenyl–3–heptanol)
(6) Dimepheptanol (6–dimethylamino–4,4–diphenyl–3–heptanol)
(7) Noracymethadol (α–6–methylamino–4,4–diphenyl–3–heptanol acetate)

7. Phenalkoxams, their salts, derivatives and salts of derivatives including:

(1) Dimenoxadol (dimethylaminoethyl 1–ethoxy–1,1–diphenylacetate)
(2) Dioxaphetylbutyrate (ethyl 2,2–diphenyl–4–morpholino butyrate)
(3) Dextropropoxyphene([S–(R*,S*)]–α–[2–(dimethylamino)–1–methylethyl]–α–phenylbenzeneethanol, propanoate ester)

8. **Thiambutenes, their salts, derivatives and salts of derivatives including:**

(1) Diethylthiambutene (N,N–diethyl–1–methyl–3,3–di–2–thienylallylamine)
(2) Dimethylthiambutene (N,N,1–trimethyl–3,3–di–2–thienylallylamine)
(3) Ethylmethylthiambutene (N–ethyl–N,1–dimethyl–3,3–di–2–thienylallylamine)

9. Moramides, their intermediates, salts, derivatives and salts of intermediates and derivatives including:

(1) Dextromoramide(d–1–(3–methyl–4–morpholino–2,2–diphenylbutyryl)pyrrolidine)
(2) Diphenylmorpholinoisovalericacid(2–methyl–3–morpholino–1,1–diphenylpropionic acid)
(3) Levomoramide (*l*–1–(3–methyl–4–morpholino–2,2–diphenylbutyryl)pyrrolidine)
(4) Racemoramide(d,l–1–(3–methyl–4–morpholino–2,2–diphenylbutyryl) pyrrolidine)

10. Morphinans, their salts, derivatives and salts of derivatives including:

(1) Buprenorphine(17–(cyclopropylmethyl)–α–(1,1–di- methylethyl)–4,5–epoxy–18,19–dihydro–3–hydroxy- –6–methoxy–α–methyl–6,14–ethenomorphinan–7- –methanol)
(2) Drotebanol (6β,14–dihydroxy–3,4–dimethoxy–17–methylmorphinan)
(3) Levomethorphan (l–3–methoxy–17–methylmorphinan)
(4) Levorphanol (l–3–hydroxy–17–methylmorphinan)
(5) Levophenacylmorphan (l–3–hydroxy–17–phenacylmorphinan)
(6) Norlevorphanol (l–3–hydroxymorphinan)
(7) Phenomorphan (3–hydroxy–17–(2–phenylethyl)morphinan)
(8) Racemethorphan (d,1–3–methoxy–17–methylmorphinan)
(9) Racemorphan (3–hydroxy–N–methylmorphinan)

But not including

(10) Dextromethorphan(d–1,2,3,9,10,10a–hexahydro–6—methoxy–11–methyl–4H–10,4a–iminoethano–phe- nanthren)

(11) Dextrorphan(d–1,2,3,9,10,10a–hexahydro–11–methyl–4H–10,4a–iminoethanophenanthren–6–ol)
(12) Levallorphan(l–11–allyl–1,2,3,9,10,10a–hexahydro–4H–10,4a–iminoethanophenanthren– 6–ol)
(13) Levangorphan(l–11–propargyl–1,2,3,9,10,10a–hexahydro–4H–10,4a–iminoethanophenanthren– 6–ol)
(14) Butorphanol (17–(cyclobutylmethyl)morphinan–3,14–diol)
(15) Nalbuphine (17–(cyclobutylmethyl)–4,5α–epoxymorphinan–3, 6α, 14– triol)

11. Benzazocines, their salts, derivatives and salts of derivatives including:

(1) Phenazocine(1,2,3,4,5,6–hexahydro–6,11–dimethyl–3–phenethyl–2,6–methano–3–benzazocin–8–ol)
(2) Metazocine(1,2,3,4,5,6–hexahydro–3,6,11–trimethyl–2,6–methano–3–benzazocin–8–ol)
(3) Pentazocine(1,2,3,4,5,6–hexahydro–6,11–dimethyl- –3–(3–methyl–2–butenyl)–2,6–methano–3–benza- zocin–8–ol)

But not including

(4) Cyclazocine(1,2,3,4,5,6–hexahydro–6,11–dimethyl–3–(cyclopropylmethyl)–2,6–methano–3–benzazocin–8–ol)

12. Ampromides, their salts, derivatives and salts of derivatives including:

(1) Diampromide (N–[2–(methylphenethylamino)pro-pyl] propionanilide)
(2) Phenampromide (N–(1–methyl–2–piperidino)ethyl) propionanilide)
(3) Propiram (N–(1–methyl–2–piperidinoethyl)–N–2–pyridylpropionamide)

13. Benzimidazoles, their salts, derivatives and salts of derivatives including:

(1) Clonitazene (2–(p–chlorobenzyl)–1–diethylaminoethyl–5–nitrobenzimidazole)
(2) Etonitazene (2–(p–ethoxybenzyl)–1–diethylaminoethyl–5–nitrobenzimidazole)
(3) Bezitramide(1–(3–cyano–3,3–diphenylpropyl)–4–(2–oxo–3–propionyl–1–benzimidazolinyl)–piperidine)

14. Phencyclidine (1–(1–phenylcyclohexyl)piperidine), its salts, derivatives and analogues and salts of derivatives and analogues

15. Piritramide(1–(3–cyano–3,3–diphenylpropyl)–4–(1–piperidino)piperidine–4–carboxylic acid amide), its salts, derivatives and salts of derivatives

6. Fentanyls, their salts, derivatives, and analogues and salts of derivatives and analogues, including:

(1) Acetyl–α–methylfentanyl(N–[1–(α–methylphen- ethyl)–4–piperidyl]acetanilide)
(2) Alfentanil(N–[1–[2–(4–ethyl–4,5–dihydro–5–oxo–1H–tetrazol–1–yl)ethyl]–4–(methoxy- methyl)–4–piperidyl] propionanilide)
(3) Carfentanil(methyl4–[(1–oxopropyl)phenylamino]–1–(2–phenethyl)–4–piperidinecarboxylate)
(4) p–Fluorofentanyl (4'fluoro–N–(1–phenethyl–4– piperidyl) propionanilide)
(5) Fentanyl (N–(1–phenethyl–4–piperidyl)propionanilide)
(6) β–Hydroxyfentanyl (N–[1– (β–hydroxyphenethyl)–4– piperidyl] propionanilide)
(7) β–Hydroxy–3–methylfentanyl (N–[1–(β–hydroxyphenethyl)–3–methyl–4–piperidyl] propionanilide)
(8) α–Methylfentanyl (N–[1–(α–methylphenethyl)–4– piperidyl] propionanilide)
(9) α–Methylthiofentanyl(N–[1–[1–methyl–2–(2–thienyl)ethyl]–4–piperidyl] propionanilide)
(10) 3–Methylfentanyl (N–(3–methyl–1–phenethyl–4– piperidyl) propionanilide)
(11) 3–Methylthiofentanyl(N–[3–methyl–1–[2–(2–thienyl)ethyl]–4–piperidyl]propionanilide)

(12) Sufentanil(N–[4–(methoxymethyl)–1–[2–(2–thienyl)ethyl]–4–piperidyl]propionanilide)
(13) Thiofentanyl (N–[1–[2–(2–thienyl)ethyl]–4–piperidyl] propionanilide)

17. Tilidine(ethyl2–(dimethylamino)–1–phenyl–3–cyclohexene–1–carboxylate), its salts, derivatives and salts of derivatives

SCHEDULE II

1. **Cannabis, its preparations, derivatives and similar synthetic preparations, including:**

(1) Cannabis resin
(2) Cannabis (marihuana)
(3) Cannabidiol(2–[3–methyl–6–(1–methylethenyl)–2–cyclohexen–1–yl]–5–pentyl–1,3–benzenediol)
(4) Cannabinol(3–n–amyl–6,6,9–trimethyl–6–diben- zopyran–1–ol)
(5) Nabilone((±)–trans–3–(1,1–dimethylheptyl)–6,6a,7,8,10,10a–hexahydro–1–hydroxy–6,6–dime- thyl–9H–dibenzo[b,d]pyran–9–one)
(6) Pyrahexyl(3–n–hexyl–6,6,9–trimethyl–7,8,9,10–tetrahydro–6–dibenzopyran–1–ol)
(7) Tetrahydrocannabinol(tetrahydro–6,6,9–trimethyl–3–pentyl–6H–dibenzo[b,d]pyran–1–ol)

But not including

(8) Non-viable Cannabis seed
(9) Mature Cannabis stalks that do not include leaves, flowers, seeds or branches; and fiber derived from such stalks

SCHEDULE III

1. Amphetamines, their salts, derivatives, isomers and analogues and salts of derivatives, isomers and analogues including:

(1) amphetamine (α–methylbenzeneethanamine)
(2) methamphetamine (N,α–dimethylbenzeneethanamine)
(3) N–ethylamphetamine (N–ethyl–α–methylbenzeneethanamine)
(4) 4–methyl–2,5–dimethoxyamphetamine(STP)(2,5–dimethoxy–4,α–dimethylbenzeneethanamine)
(5) 3,4–methylenedioxyamphetamine(MDA)(α–methyl–1,3–benzodioxole–5–ethanamine)
(6) 2,5–dimethoxyamphetamine (2,5–dimethoxy–α–methylbenzeneethanamine)
(7) 4–methoxyamphetamine (4–methoxy–α–methylbenzeneethanamine)
(8) 2,4,5–trimethoxyamphetamine(2,4,5–trimethoxy–α–methylbenzeneethanamine)
(9) N–methyl–3,4–methylenedioxyamphetamine(N,α–dimethyl–1,3–benzodioxole–5–et
hanamine)
(10) 4–ethoxy–2,5–dimethoxyamphetamine(4–ethoxy–2,5–dimethoxy–α–methylbenzeneethanamine
(11) 5–methoxy–3,4–methylenedioxyamphetamine(7–methoxy–α–methyl–1,3–benzodioxole–5–ethanamine)
(12) N,N–dimethyl–3,4–methylenedioxyamphetamine(N,N,α–trimethyl–1,3–benzodioxole–5–ethanamine)
(13) N–ethyl–3,4–methylenedioxyamphetamine(N–ethyl–α–methyl–1,3–benzodioxole–5–ethanamine)
(14) 4–ethyl–2,5–dimethoxyamphetamine(DOET) (4–ethyl–2,5–dimethoxy–α–methylbenzeneethana- mine)
(15) 4–bromo–2,5–dimethoxyamphetamine(4–bromo–2,5–dimethoxy–α–methylbenzeneethanamine)
(16) 4–chloro–2,5–dimethoxyamphetamine(4–chloro–2,5–dimethoxy–α–methylbenzeneethanamine)
(17) 4–ethoxyamphetamine (4–ethoxy–α–methylbenzeneethanamine)
(18) Benzphetamine (N–benzyl–N,α–dimethylbenzeneethanamine)
(19) N–Propyl–3,4–methylenedioxyamphetamine(α–methyl–N–propyl–1,3–benzodioxole–5–ethanamine)
(20) N- (2-Hydroxyethyl) -α -methylbenzeethanamine

2. Methylphenidate (α–phenyl–2–pyridineacetic acid methyl ester) and any salt thereof

3. Methaqualone (2–methyl–3–(2–methylphenyl)–4(3H)–quinazolinone) and any salt thereof
4. Mecloqualone (2–methyl–3–(2–chlorophenyl)–4(3H)–quinazolinone) and any salt thereof
5. Lysergic acid diethylamide (LSD) (N,N–diethyllysergamide) and any salt thereof
6. N,N–Diethyltryptamine (DET) (3–[(2–diethylamino)ethyl]indole) and any salt thereof
7. N,N–Dimethyltryptamine (DMT) (3–[(2–dimethylamino)ethyl]indole) and any salt thereof
8. N–Methyl–3–piperidyl benzilate(LBJ)(3–[(hydroxydiphenylacetyl)oxy]–1–methylpiperidine) and any salt thereof
9. Harmaline (4,9–dihydro–7–methoxy–1–methyl–3H–pyrido(3,4–b)indole) and any salt thereof
10. Harmalol (4,9–dihydro–1–methyl–3H–pyrido(3,4–b)indol–7–ol) and any salt thereof
11. Psilocin (3–[2–(dimethylamino)ethyl]–4–hydroxyindole) and any salt thereof
12. Psilocybin(3–[2–(dimethylamino)ethyl]–4–phosphoryloxyindole) and any salt thereof
13. N–(1–phenylcyclohexyl)ethylamine (PCE) and any salt thereof
14. 1–[1–(2–Thienyl) cyclohexyl]piperidine (TCP) and any salt thereof
15. 1–Phenyl–N–propylcyclohexanamine and any salt thereof
16. 1–(1–Phenylcyclohexyl)pyrrolidine and any salt thereof
17. Mescaline (3,4,5–trimethoxybenzeneethanamine) and any salt thereof, but not peyote (lophophora)

18. 4–Methylaminorex(4,5–dihydro–4–methyl–5–phenyl–2–oxazolamine) and any salt thereof
19. Cathinone(–)–α–aminopropiophenone) and any salt thereof
20. Fenetylline(d,l–3,7–dihydro–1,3–dimethyl–7–(2–[(1–methyl–2–phenethyl)amino]ethyl)–1H–purine–2,6–dione) and any salt thereof
21. 2–Methylamino–1–phenyl–1–propanone and any salt thereof
22. 1–[1–(Phenylmethyl)cyclohexyl]piperidine and any salt thereof
23. 1–[1–(4–Methylphenyl)cyclohexyl]piperidine and any salt thereof
24. 4-bromo-2,5-dimethoxybenzeneethanamine and any salt, isomer or salt of isomer therefor.
25. Flunitrazepam(5-(o-fluorophenyl)-1,3-dihydro-1-methyl-7-nitro-2H-1,4-benzodiazepin-2-one)
26. 4-hydroxybutanoic acid (GHB) and any salt thereof

SCHEDULE IV

1. Barbiturates, their salts and derivatives including

(1) Allobarbital (5,5–diallylbarbituric acid)
(2) Alphenal (5–allyl–5–phenylbarbituric acid)
(3) Amobarbital (5–ethyl–5–(3–methylbutyl)barbituric acid)
(4) Aprobarbital (5–allyl–5–isopropylbarbituric acid)
(5) Barbital (5,5–diethylbarbituric acid)
(6) Barbituric Acid (2,4,6(1H,3H,5H)–pyrimidinetrione)
(7) Butabarbital (5–sec–butyl–5–ethylbarbituric acid)
(8) Butalbital (5–allyl–5–isobutylbarbituric acid)
(9) Butallylonal (5–(2–bromoallyl)–5–sec–butylbarbituric acid)
(10) Butethal (5–butyl–5–ethylbarbituric acid)
(11) Cyclobarbital (5–(1–cyclohexen–1–yl)–5–ethylbarbituric acid)
(12) Cyclopal (5–allyl–5–(2–cyclopenten–1–yl)barbituric acid)
(13) Heptabarbital (5–(1–cycloheptен–1–yl)–5–ethylbarbituric acid)
(14) Hexethal (5–ethyl–5–hexylbarbituric acid)
(15) Hexobarbital (5–(1–cyclohexen–1–yl)–1,5–dimethylbarbituric acid)
(16) Mephobarbital (5–ethyl–1–methyl–5–phenylbarbituric acid)
(17) Methabarbital (5,5–diethyl–1–methylbarbituric acid)
(18) Methylphenobarbital (5–ethyl–1–methyl–5–phenylbarbituric acid)
(19) Propallylonal (5–(2–bromoallyl)–5–isopropylbarbituric acid)
(20) Pentobarbital (5–ethyl–5–(1–methylbutyl)barbituric acid
(21) Phenobarbital (5–ethyl–5–phenylbarbituric acid)
(22) Probarbital (5–ethyl–5–isopropylbarbituric acid)
(23) Phenylmethylbarbituric Acid (5–methyl–5–phenylbarbituric acid)
(24) ecobarbital (5–allyl–5–(1–methylbutyl)barbituric acid)
(25) Sigmodal (5–(2–bromoallyl)–5–(1–methylbutyl)barbituric acid)
(26) Talbutal (5–allyl–5–sec–butylbarbituric acid)
(27) Vinbarbital (5–ethyl–5–(1–methyl–1–butenyl)barbituric acid)
(28) Vinylbital (5–(1–methylbutyl)–5–vinylbarbituric acid)

2. Thiobarbiturates, their salts and derivatives including:

(1) Thialbarbital (5–allyl–5–(2–cyclohexen–1–yl)–2–thiobarbituric acid)
(2) Thiamylal (5–allyl–5–(1–methylbutyl)–2–thiobarbituric acid)
(3) Thiobarbituric Acid (2–thiobarbituric acid)
(4) Thiopental (5–ethyl–5–(1–methylbutyl)–2–thiobarbituric acid)

3. Chlorphentermine (1–(p–chlorophenyl)–2–methyl–2–aminopropane) and any salt thereof

4. **Diethylpropion (2–(diethylamino)propiophenone) and any salt thereof**
5. **Phendimetrazine (d–3,4–dimethyl–2–phenylmorpholine) and any salt thereof**
6. **Phenmetrazine (3–methyl–2–phenylmorpholine) and any salt thereof**
7. **Pipradol (α,α–diphenyl–2–piperidinemethanol) and any salt thereof**
8. **Phentermine (α,α–dimethylbenzeneethanamine) and any salt thereof**
9. **Butorphanol (l–N–cyclobutylmethyl–3,14–dihydroxymorphinan) and any salt thereof**
10. **Nalbuphine (N–cyclobutylmethyl–4,5–epoxy–morphinan–3,6,14–triol) and any salt thereof**
11. **Glutethimide (2–ethyl–2–phenylglutarimide)**
12. **Clotiazepam (5–(o–chlorophenyl)–7–ethyl–1,3–dihydro–1–methyl–2H–thieno[2,3–e]–1,4–diazepin–2–one)**
13. **Ethchlorvynol (ethyl–2–chlorovinyl ethynyl carbinol)**
14. **Ethinamate (1–ethynylcyclohexanol carbamate)**
15. **Mazindol (5–(p–chlorophenyl)–2,5–dihydro–3H–imidazo[2,1–a]isoindol–5–ol)**
16. **Meprobamate (2–methyl–2–propyl–1,3–propanediol dicarbamate)**
17. **Methyprylon (3,3–diethyl–5–methyl–2,4–piperidinedione)**
18. **Benzodiazepines, their salts and derivatives, including:**

(1) Alprazolam(8–chloro–1–methyl–6–phenyl–4H–s–triazolo[4,3–a][1,4]benzodiazepine)
(2) Bromazepam(7–bromo–1,3–dihydro–5–(2–pyridyl)–2H–1,4–benzodiazepin–2–one)
(3) Camazepam(7–chloro–1,3–dihydro–3–(N,N–dime-thylcarbamoyl)–1–methyl–5–phenyl–2H–1,4–ben- zodiazepin–2–one)
(4) Chlordiazepoxide(7–chloro–2–(methylamino)–5–phenyl–3H–1,4–benzodiazepine–4–oxide)

(5) Clobazam(7–chloro–1–methyl–5–phenyl–1H–1,5–benzodiazepine–2,4(3H,5H)–dione)
(6) Clonazepam(5–(o–chlorophenyl)–1,3–dihydro–7–nitro–2H–1,4–benzodiazepin–2–one)
(7) Clorazepate(7–chloro–2,3–dihydro–2,2–dihydroxy–5–phenyl–1H–1,4–benzodiazepine–3–carboxylic acid)
(8) Cloxazolam(10–chloro–11b–(o–chlorophenyl)–2,3,7,11b–tetrahydrooxazolo[3,2–d][1,4]benzodiazepin–6(5H)–one)
(9) Delorazepam(7–chloro–5–(o–chlorophenyl)–1,3–dihydro–2H–1,4–benzodiazepin–2–one)
(10) Diazepam(7–chloro–1,3–dihydro–1–methyl–5–phenyl–2H–1,4–benzodiazepin–2–one)
(11) Estazolam (8–chloro–6–phenyl–4H–s–triazolo[4,3–a] [1,4]benzodiazepine)
(12) EthylLoflazepate(ethyl7–chloro–5–(o–fluorophen-yl)–2,3–dihydro–2–oxo–1H–1,4–benzodiazepine–3- –carboxylate)
(13) Fludiazepam(7–chloro–5–(o–fluorophenyl)–1,3–dihydro–1–methyl–2H–1,4–benzodiazepin–2–one)
(14) "Repealed"
(15) Flurazepam(7–chloro–1–[2–(diethylamino)ethyl]–5–(o–fluorophenyl)–1,3–dihydro–2H–1,4–benzodiaze- pin–2–one)
(16) Halazepam(7–chloro–1,3–dihydro–5–phenyl–1–(2,2,2–trifluoroethyl)–2H–1,4–benzodiazepin–2–one)
(17) Haloxazolam(10–bromo–11b–(o–fluorophenyl)–2,3,-7,11b–tetrahydrooxazolo[3,2–d][1,4]benzodiazepin- –6(5H)–one)
(18) Ketazolam(11–chloro–8,12b–dihydro–2,8–dimeth-yl–12b–phenyl–4H–[1,3]–oxazino–[3,2–d][1,4]benzo- diazepine–4,7(6H)–dione)
(19) Loprazolam(6–(o–chlorophenyl)–2,4–dihydro–2–[(4–methyl–1–piperazinyl)methylene]–8–nitro–1H- –imidazo[1,2–a][1,4]benzodiazepin–1–one)
(20) Lorazepam(7–chloro–5–(o–chlorophenyl)–1,3–dihydro–3–hydroxy–2H–1,4–benzodiazepin–2–one)
(21) Lormetazepam(7–chloro–5–(o–chlorophenyl)–1,3–dihydro–3–hydroxy–1–methyl–2H–1,4–benzodiaze- pin–2–one)
(22) Medazepam(7–chloro–2,3–dihydro–1–methyl–5–phenyl–1H–1,4–benzodiazepine)
(23) Nimetazepam(1,3–dihydro–1–methyl–7–nitro–5–phenyl–2H–1,4–benzodiazepin–2–one)
(24) Nitrazepam (1,3–dihydro–7–nitro–5–phenyl–2H–1,4–benzodiazepin–2–one)
(25) Nordazepam(7–chloro–1,3–dihydro–5–phenyl–1(2H)–1,4–benzodiazepin–2–one
(26) Oxazepam(7–chloro–1,3–dihydro–3–hydroxy–5–phenyl–2H–1,4–benzodiazepin–2–one)

(27) Oxazolam(10–chloro–2,3,7,11b–tetrahydro–2–methyl–11b–phenyloxazolo[3,2–d][1,4]benzodiazepin- –6(5H)–one)
(28) Pinazepam(7–chloro–1,3–dihydro–5–phenyl–1–(2–propynyl)–2H–1,4–benzodiazepin–2–one)
(29) Prazepam(7–chloro–1–(cyclopropylmethyl)–1,3–dihydro–5–phenyl–2H–1,4–benzodiazepin–2–one)
(30) Temazepam(7–chloro–1,3–dihydro–3–hydroxy–1–methyl–5–phenyl–2H–1,4–benzodiazepin–2–one)
(31) Tetrazepam(7–chloro–5–(cyclohexen–1–yl)–1,3–dihdyro–1–methyl–2H–1,4–benzodiazepin–2–one)
(32) Triazolam(8–chloro–6–(o–chlorophenyl)–1–methyl–4H–s–triazolo[4,3–a][1,4]benzodiazepine)

But not including

(33) Flunitrazepam(5-(o-fluorophenyl)-1,3-dihydro-1methyl-7-nitro-2H-1,4-benzodiazepin-2-one)

19. Catha edulis Forsk., its preparations, derivatives, alkaloids and salts, including:
(1) Cathine (d–threo–2–amino–1–hydroxy–1–phenylpropane)

20. Fencamfamin (d,l–N–ethyl–3–phenylbicyclo[2,2,1]heptan–2–amine) and any salt thereof

21. Fenproporex (d,l–3–[(α–methylphenethyl)amino]propionitrile) and any salt thereof

22. Mefenorex (d,l–N–(3–chloropropyl)–α–methylbenzeneethanamine) and any salt thereof

23. Anabolic steroids and their derivatives including:
(1) Androisoxazole (17β–hydroxy–17α–methylandrostano[3,2–c]isoxazole)
(2) Androstanolone (17β–hydroxy–5α–androstan–3–one)
(3) Androstenediol (androst–5–ene–3β,17β–diol)
(4) Bolandiol (estr–4–ene–3β,17β–diol)
(5) Bolasterone (17β–hydroxy–7α,17–dimethylandrost–4–en–3–one)
(6) Bolazine (17β–hydroxy–2α–methyl–5α–androstan–3–one azine)
(7) Boldenone (17β–hydroxyandrosta–1,4–dien–3–one)
(8) Bolenol (19–nor–17α–pregn–5–en–17–ol)
(9) Calusterone (17β–hydroxy–7β,17–dimethylandrost–4–en–3–one)

(10) Clostebol (4–chloro–17β–hydroxyandrost–4–en–3–one)
(11) Drostanolone (17β–hydroxy–2α–methyl–5α–androstan–3–one)
(12) Enestebol (4, 17β–dihydroxy–17–methylandrosta–1,4–dien–3–one)
(13) Epitiostanol (2α, 3α–epithio–5α–androstan–17β–ol)
(14) Ethylestrenol (19–nor–17α–pregn–4–en–17–ol)
(15) 4–Hydroxy–19–nor testosterone
(16) Fluoxymesterone(9–fluoro–11β,17β–dihydroxy–17–methylandrost–4–en–3–one)
(17) Formebolone(11α,17β–dihydroxy–17–methyl–3–oxoandrosta–1,4–dien–2–carboxaldehyde)
(18) Furazabol (17–methyl–5α–androstano[2,3–c]furazan–17β–ol)
(19) Mebolazine (17β–hydroxy–2α,17–dimethyl–5α–androstan–3–one azine)
(20) Mesabolone (17β–[(1–methoxycyclohexyl)oxy]–5α–androst–1–en–3–one)
(21) Mesterolone (17β–hydroxy–1α–methyl–5α–androstan–3–one)
(22) Metandienone (17β–hydroxy–17–methylandrosta–1,4–dien–3–one)
(23) Metenolone (17β–hydroxy–1–methyl–5α–androst–1–en–3–one)
(24) Methandriol (17α–methylandrost–5–ene–3β,17β–diol)
(25) Methyltestosterone (17β–hydroxy–17–methylandrost–4–en–3–one)
(26) Metribolone (17β–hydroxy–17–methylestra–4, 9,11–trien–3–one)
(27) Mibolerone (17β–hydroxy–7α,17–dimethylestr–4–en–3–one)
(28) Nandrolone (17β–hydroxyestr–4–en–3–one)
(29) Norboletone (13–ethyl–17β–hydroxy–18,19–dinorpregn–4–en–3–one)
(30) Norclostebol (4–chloro–17β–hydroxyestr–4–en–3–one)
(31) Norethandrolone (17α–ethyl–17β–hydroxyestr–4–en–3–one)
(32) Oxabolone (4,17β–dihydroxyestr–4–en–3–one)
(33) Oxandrolone (17β–hydroxy–17–methyl–2–oxa- –5α–androstan–3–one)
(34) Oxymesterone (4,17β–dihydroxy–17–methylandrost–4–en–3–one)
(35) Oxymetholone(17β–hydroxy–2–(hydroxymethylene)–17–methyl–5α–androstan–3–one)
(36) Prasterone (3β–hydroxyandrost–5–en–17–one)
(37) Quinbolone (17β–(1–cyclopenten–1–yloxy)androsta–1,4–dien–3–one)
(38) Stanozolol (17β–hydroxy–17–methyl–5α–androstano[3,2–c]pyrazole)
(39) Stenbolone (17β–hydroxy–2–methyl–5α–androst–1–en–3–one)
(40) Testosterone (17β–hydroxyandrost–4–en–3–one)
(41) Tibolone (17–hydroxy–7α–methyl–19–norpregn–5(10)–en–20–yn–3–one)
(42) Tiomesterone(1α,7α–bis(acetylthio)–17β–hydroxy–17–methylandrost–4–en–3–one
(43) Trenbolone (17β–hydroxyestra–4,9,11–trien–3–one)

24. Zeranol (3,4,5,6,7,8,9,10,11,12–decahydro–7,14,16–trihydroxy–3–methyl–1H–2 –benzoxacyclotetradecin–1–one)

SCHEDULES I to IV - SYNONYMS

The following is a partial list of substances referred to in Schedules I to IV of the *Controlled Drugs and Substances Act* and their synonyms. The synonyms for these substances are commonly found on labelling information.

The listing is not to duplicate the preceding list in this Section but to provide synonyms for those substances where other names are commonly used.

CATHA EDULIS

Synonyms:
Chat, catha, cathine, celastraceae, Khat.
Regulatory authority:
CDSA Schedule IV.

Note: Cathinone, a constituent of *catha edulis*, is listed in CDSA Schedule III.

PRASTERONE

Synonyms:
Dehydroepiandrosterone (DHEA), dehydroisoandrosterone, trans-dehydroabdrosterone, DHEAS, DHEA-sulfate.
Regulatory authority:
CDSA Schedule IV.

SEX HORMONES WITH ANABOLIC ACTIVITY

Regulatory authority:
CDSA Schedule IV.
Note: Examples include androgens (testosterone and testosterone derivatives) and anabolic steroids such as boldenone, formebolone, norclostebol, oxabolone, trenbolone, etc. **This is not an exhaustive list.**

1.3.2 Schedule D (except whole blood and its components) of the *Food and Drugs Act*

The following is the list of substances referred to in Schedule D of the *Food and Drugs Act*.

Allergenic substances used for the treatment or diagnosis of allergic or immunological diseases
Anterior pituitary extracts
Aprotinin
Blood and blood derivatives *(The Interim DIN Directive does not cover blood and blood components)*
Cholecystokinin
Drugs obtained by recombinant DNA procedures
Drugs, other than antibiotics, prepared from micro-organisms
Glucagon
Gonadotrophins
Human plasma collected by plasmapheresis
Immunizing agents
Insulin
Interferon
Monoclonal antibodies, their conjuguates and derivatives
Secretin
Snake Venom
Urokinase

1.3.3 Substances listed in Schedule F in the *Food and Drug Regulations*

SCHEDULE F - PART I (FDR)

The following is the list of substances referred to in Part I of Schedule F of the *Food and Drug Regulations*.

Abciximab
Acarbose and its derivatives
Acebutolol and its salts
Acetazolamide
Acetohexamide
Acetylcarbromal
Acetylcholine Chloride
Acitretin and its salts and derivatives
Aconiazide and its salts
Acyclovir and its salts
Adapalene and its salts and derivatives
Adenosine and its salts, when sold or recommended for administration by intravenous injection
Aldesleukin
Alendronic acid and its salts
Alfacalcidol
Alkyl nitrites
Allopurinol
Allylisopropylacetylurea
Alpha-chloralose
Alphadolone and its salts
Alphaxalone
Alprazolam
Altrenogest
Altretamine
Amantadine and its salts
Ambenonium Chloride
Amifostine and its salts
Amikacin and its salts and derivatives
Amiloride and its salts
Aminocaproic acid
Aminoglutethimide

Aminophylline
Aminopterin and its salts
4-Amino-pteroyl aspartic acid and its salts
5-Aminosalicylic acid
4-Aminosalicylic Acid and its salts
Amiodarone and its salts
Amitraz
Amitriptyline and its salts
Amlodipine and its salts
Ammonium bromide
Amoxapine
Amoxicillin and its salts and derivatives
Amphotericin B and its salts and derivatives
Ampicillin and its salts and derivatives
Amrinone and its salts
Amsacrine and its salts
Anastrozole
Apiol, oil of
Apraclonidine and its salts
Aprotinin
L-Asparaginase
Astemizole and its salts
Atenolol and its salts
Atorvastatin and its salts
Atovaquone
Atracurium besilate
Atropine and its salts in ophthalmic or parenteral preparations only
Auranofin
Aurothioglucose
Azacyclonol and its salts
Azaribine
Azathioprine and its salts
Azatidine and its salts
Azlocillin and its salts and derivatives
Aztreonam and its salts
Baclofen and its salts
Bambuterol and its salts
Bemegride
Benactyzine and its salts
Benazepril and its salts and derivatives
Bendazac and its salts
Benoxaprofen and its salts

Benserazide and its salts
Benzathine penicillin and its salts and derivatives
Benzoyl peroxide in concentrations greater than 5 per cent or when sold in combination with another medicinal ingredient
Benztropine and its salts
Benzydamine and its salts
Beractant
Betahistine and its salts
Betaxolol and its salts
Bethanechol chloride
Bethanidine and its salts
Bezafibrate and its salts and derivatives
Bicalutamide
Biperiden and its salts
Bishydroxycoumarin and its salts and derivatives
Bisoprolol and its salts
Bitolterol and its salts
Bleomycin
Botulinum Toxin Type A
Bretylium tosylate
Bromal
Bromal hydrate
Bromazepam and its salts
Brometone
Bromisoval
Bromocriptine and its salts
Bromoform
Bumetanide and its salts and derivatives
Buserelin and its salts
Buspirone and its salts
Busulfan
Butaperazine and its salts
Butoconazole and its salts
Butyl chloral hydrate
Calcipotriol
Calcitonin
Calcitriol
Calcium bromide
Calcium bromolactobionate
Calcium carbimide
Candicidin and its salts and derivatives
Capreomycin and its salts and deriviatives

Captodiamine and its salts
Captopril and its salts
Carbachol
Carbamazepine
Carbenicillin and its salts and derviatives
Carbenoxolone and its salts
Carbidopa and its salts
Carbimazole
Carbocisteine
Carbomycin and its salts and derivatives
Carboplatin
Carbromal
Carisoprodol
Carmustine
Carphenazine and its salts
Carvedilol and its salts
Cefepime and its salts and derivatives
Cefonicide and its salts
Cefoperazone and its salts and derivatives
Cefprozil and its salts and derivatives
Ceftibuten and its salts and derivatives
Cephalosporin C and its salts and derivatives
Cetirizine and its salts when sold in concentrations greater than 8.5 mg cetirizine per unit dose
Chloral
Chloral hydrate
Chloralformamide
Chloralimide
Chlorambucil and its salts and derivatives
Chloramphenicol and its salts and derivatives
Chlorcyclizine and its salts (except in preparations for external use only)
Chlordiazepoxide and its salts
Chlorisondamine and its salts
Chlormezanone
Chloroquine and its salts
Chlorpropamide
Chlorprothixene and its salts
Choline salicylate, when sold in combination with magnesium salicylate
Choline theophyllinate
Ciclopirox and its salts
Cilastatin and its salts
Cilazapril and its salts and derivatives

Cimetidine and its salts when sold in concentrations greater than 100 mg of cimetidine per unit dose
Cinchophene and its salts
Cinoxacin
Ciprofloxacin and its salts
Cisapride and its salts
Cisatracurium besilate
Cisplatin
Cladribine and its salts
Clenbuterol and its salts
Clobazam and its salts
Clodronic acid and its salts
Clofibrate
Clomiphene and its salts
Clomipramine and its salts
Clonazepam and its salts
Clonidine and its salts
Cloprostenol and its salts and derivatives
Clorazepic acid and its salts
Clotrimazole and its salts (except in preparations for topical and vaginal use)
Cloxacillin and its salts and deriviatives
Clozapine and its salts
Colchicine
Colestipol and its salts
Colfosceril and its derivatives
Colistin and its salt and derivatives
Cromoglicic acid and its salts (except sodium cromoglycate in solutions for ophthalmic or nasal use in concentrations of 2 % or less)
Cyclobenzaprine and its salts
Cyclopentolate and its salts in preparations for parenteral or ophthalmic use, except when sold for use in diagnostic procedures to an optometrist registered in a province of Canada
Cyclophosphamide
Cycloserine
Cyclosporine
Cyproterone acetate
Cytarabine and its salts
Dacarbazine
Dactinomycin
Dalteparin and its salts
Danaparoid and its salts and derivatives
Danazol

Dantrolene and its salts
Dapiprazole and its salts
Daunorubicin and its salts
Deanol, and its salts and derivatives
Debrisoquin and its salts
Deferoxamine and its salts
Deserpidine and its alkaloids and salts
Desflurane
Desipramine and its salts
Desmopressin and its salts
Detomidine and its salts
Dexfenfluramine and its salts
Dexrazoxane and its salts
Diazepam and its salts
Diazoxide and its salts
Dichloroacetic Acid
Diclofenac and its salts
Dicloxacillin and its salts and derivatives
Didanosine and its salts and derivatives
Diethylbromacetamide
Diethylcarbamazine and its salts
Diethylstilbestrol and its salts and derivatives
Diflunisal and its salts
Digitalis lanata and its glycosides
Digitalis purpurea and its glycosides
Digoxin immune Fab (ovine)
Dihydrotachysterol
Diiodohydroxyquin (except in preparations for topical use on the skin)
Diltiazem and its salts
Dimercaprol
Dimethyl sulfoxide
2,4-Dinitrophenol and its salts and derivatives
Dinoprostone and its salts and derivatives
Diphenidol and its salts
Diphenylhydantoin (phenytoin) and its salts
Dipivefrin and its salts
Diprophylline and its salts
Dipyridamole
Disopyramide and its salts
Disulfiram
Dobutamine and its salts
Docetaxel and its derivatives

Dolasetron and its salts
Domperidone
Donepezil and its salts
Dopamine and its salts
Dornase alfa
Dorzolamide and its salts
Doxacurium chloride
Doxapram
Doxazosin and its salts
Doxepin and its salts
Doxorubicin and its salts
Doxycycline and its salts and derivatives, when sold for intramuscular administration in caged birds
Doxylamine and its salts, when sold or recommended for use in the nausea or vomiting of pregnancy
Droperidol and its salts
Econazole and its salts
Ecothiophate and its salts
Ectylurea and its salts
Edrophonium chloride
Embutramide
Emylcamate
Enalaprilat and its salts and derivatives
Enflurane
Enoxaparin and its salts
Enrofloxacin
Epirubicine and its salts
Epoprostenol and its salts
Erythropoietin
Esmolol and its salts
Estazolam and its salts
Estramustine and its salts
Ethacrynic acid
Ethambutol and its salts
Ethchlorvynol
Ethinamate
Ethionamide and its salts
Ethomoxane and its salts
Ethotoin and its salts
Ethyl trichloramate
Etidronic acid and its salts
Etodolac and its salts and derivatives

Etoposide and its derivatives
Etretinate
Etryptamine and its salts
Etymemazine and its salts
Famciclovir and its salts
Famotidine and its salts (except in preparations for oral use containing 10 mg or less of famotidine per dosage unit)
Felodipine and its salts
Fenfluramine and its salts
Fenofibrate
Fenoprofen and its salts
Fenoterol and its salts
Filgrastim
Finasteride
Flavoxate and its salts
Flecainide and its salts
Fleroxacin and its salts and derivatives
Floctafenine
Florfenicol and its derivatives
Fluconazole
Flucytosine
Fludarabine and its salts and derivatives
Flunarizine and its salts
Flunixin and its salts and derivatives
Fluorouracil and its derivatives
Fluoxetine and its salts
Flupentixol and its salts and derivatives
Fluphenazine and its salts
Fluprostenol and its salts and derivatives
Flurazepam and its salts
Flurbiprofen and its salts
Fluspirilene
Flutamide
Fluvastatin and its salts and derivatives
Fluvoxamine and its salts
Folic acid (oral dosage form containing more than 1.0 mg or where daily dosage is more than 1.0 mg.
Follicle stimulating hormone
Formestane and its derivatives
Foscarnet sodium
Fosinopril and its salts
Fosphenytoin and its salts

Fusidic acid and its salts
Gabapentin and its salts and derivatives
Gallamine triethiodide
Gallium and its salts
Ganciclovir and its salts
Gemcitabine and its salts
Gemfibrozil and its salts
Gentamicin and its salts and derivatives
Glatiramer and its salts
Gliclazide
Glipizide
Glutethimide
Glyburide and its salts and derivatives
Gold and its salts
Gonadorelin and its salts
Gonadotropin, chorionic (human)
Gonadotropins, serum (human)
Goserelin and its salts
Granisetron and its salts
Guanethidine and its salts
Halazepam and its salts
Halofantrine and its salts
Haloperidol
Halothane
Hetacillin and its salts and derivatives
Hexachlorophene and its salts
Hexacyclonate sodium
Hexamethonium and its salts
Hyaluronic acid and its salts, when sold or recommended for administration by intra-articular
injection to horses
Hydralazine and its salts
Hydroxychloroquine and its salts
4-Hydroxycoumarin and its derivatives when sold or recommended as anticoagulants
Hydroxyurea
Hydroxyzine and its salts and derivatives
Ibuprofen and its salts when sold in strengths greater than 200 mg per dosage form
Idarubicin and its salts
Idoxuridine
Ifosfamide
Imiglucerase
Imipenem and its salts and derivatives

Imipramine and its salts
Indapamide and its salts
Indinavir and its salts
Indomethacin
Inosiplex
Interferon
Iodochlorohydroxyquin (except in preparations for topical use on the skin)
Ipratropium and its salts
Iproniazid and its salts
Irinotecan and its salts
Isocarboxazid and its salts
Isoflurane
Isoniazid
Isoproterenol (Isoprenaline) and its salts
Isotretinoin and its salts
Isoxsuprine and its salts
Isradipine and its salts
Itraconazole and its salts
Ketamine and its salts
Ketazolam and its salts
Ketoconazole and its salts (except in preparations for topical use as a shampoo)
Ketoprofene and its salts
Ketorolac and its salts
Ketotifen and its salts
Labetalol and its salts
Lactic acid, when recommended for parenteral use as a tissue sclerosing agent
Lamivudine and its salts
Lamotrigine and its salts
Lansoprazole and its salts
Latanoprost
Letrozole
Leucovorin and its salts
Leuprolide and its salts
Levobunolol and its salts
Levocabastine and its salts and derivatives
Levocarnitine and its salts and derivatives
Levodopa and its salts
Lisinopril and its salts and derivatives
Lithium and its salts
Lodoxamide and its salts and derivatives
Lomefloxacin and its salts
Lomustine

Loracarbef and its salts and derivatives
Losartan and its salts
Losoxantrone and its salts
Lovastatin
Lorazepam and its salts
Loxapine and its salts
Magnesium glutamate hydrobromide
Maprotiline and its salts
Mazindol and its salts
Mecamylamine and its salts
Mechlorethamine and its salts
Mecillinam and its salts and derivatives
Meclofenamic acid and its salts
Mefenamic acid and its salts
Mefloquine and its salts and derivatives
Megestrol and its salts
Melphalan
Menotropins (human)
Mepacrine and its salts
Mepazine and its salts
Mephenoxalone
Mephentermine and its salts
Meprobamate
Mercaptopurine
Meropenem and its salts and derivatives
Mesna
Mesoridazine and its salts
Metaldehyde
Metformin and its salts and derivatives
Methicillin and its salts and derivatives
Methimazole
Methisazone
Methoin (Mephenytoin) and its salts
Methotrexate and its salts
Methotrimeprazine and its salts
Methoxamine and its salts
Methoxsalen
Methyldopa and its salts
Methylparafynol
Methyprylon
Methysergide and its salts and derivatives
Metoclopramide

Metolazone and its salts
Metomidate and its salts
Metopimazine and its salts
Metropolol and its salts
Metronidazole
Metyrapone and its salts
Mexiletine and its salts
Mezlocillin and its salts and derivatives
Miconazole and its salts (except in preparations for topical and vaginal use)
Midazolam and its salts
Midodrine and its salts
Milbemycin and its derivatives
Milrinone and its salts
Minoxidil
Mitomycin and its salts
Mitotane (o,p'-DDD)
Mitoxantrone and its salts
Mivacurium chloride
Molgramostin
Mycophenolic and its salts and derivatives
Nabumetone
Nadolol and its salts
Nafarelin and its salts and derivatives
Nafcillin and its salts and derivatives
Nalidixic acid
Naloxone and its salts
Naltrexone and its salts
Naproxen and its salts
Nedocromil and its salts
Nefazodone and its salts
Neocinchophen and its salts
Neostigmine salts
Netilmicin and its salts and derivatives
Nialamide and its salts
Nicardipine and its salts
Nicotine and its salts (except in natural substances or when sold as a chewing gum containing not more than the equivalent of 4mg of nicotine per dosage unit or when sold as a transdermal patch with a delivery rate of not more than the equivalent of 22mg of nicotine per day).
Nifedipine
Nilutamide
Nimodipine and its salts

Nitrazepam and its salts
Nizatidine and its salts (except when sold in an oral dosage form containing not more than the equivalent of 75mg of nizatidine).
Nomifensine and its salts
Norfloxacin
Nortriptyline and its salts
Nylidrin and its salts
Octatropine methylbromide
Octreotide
Ofloxacin and its salts
Olopatadine and its salts
Olsalazine and its salts
Omeprazole
Ondansetron and its salts
Orciprenaline (Metaproterenol) and its salts
Ormetoprim and its salts
Ornidazole
Oxacillin, and its salts and derivatives
Oxanamide
Oxaprozin and its salts and derivatives
Oxazepam and its salts
Oxolinic acid and its salts
Oxprenolol and its salts
Oxybutynin and its salts
Oxyphenbutazone and its salts
Oxytocin
Paclitaxel and its derivatives
Pamidronic acid and its salts
Pancuronium and its salts
Pantoprazole and its salts
Paraldehyde
Paramethadione
Pargyline and its salts
Paroxetine and its salts
Pemoline and its salts
Penicillamine
Pentamidine and its salts
Pentolinium tartrate
Pentosan polysulfate and its salts
Pentostatin and its salts
Pentoxifylline and its salts
Pergolide and its salts

Pericyazine and its salts
Perindopril and its salts
Perphenazine and its salts
Phacetoperane and its salts
Phenacemide
Phenacetin
Phenaglycodol
Phenazopyridine and its salts
Phenelzine and its salts
Phenformin and its salts
Pheniprazine and its salts
Phenthoxate and its salts
Phentolamine and its salts
Phenylbutazone and its salts
Phenylephrine and its salts in preparations for ophthalmic or parenteral use in concentrations greater than 2.5%
Phenylindanedione and its derivatives
Pilocarpine and its salts
Pimozide
Pinaverium bromide
Pindolol and its salts
Pipecuronium bromide
Piperacetazine and its salts
Piperilate and its salts
Pipotiazine and its salts
Pipobroman
Pipradol and its salts
Pirbuterol and its salts
Pirenzepine and its salts
Piroxicam and its salts
Pizotyline and its salts
Podophyllum and the following extracts and active principles, when sold or recommended for
topical use:
(a) podophyllotoxin
(b) podophyllum resin
Polysulfated glycosaminoglycan
Porfimer and its salts
Potassium bromide
Potassium gluconate, when sold or recommended for administration to cats
Potassium para-aminobenzoate (except in preparations for topical use on the skin)
Pralidoxime and its salts

Pravastatin and its salts
Prazepam and its salts
Prazosin and its salts
Prenylamine and its salts
Primaquine and its salts
Probenecid and its salts
Probucol
Procainamide and its salts
Procarbazine and its salts
Procaterol and its salts
Prochlorperazine and its salts
Procyclidine and its salts
Prodilidine and its salts
Profenamine and its salts
Proguanil and its salts
Propafenone and its salts
Propofol
Propranolol and its salts
Prostaglandins and their salts and derivatives
Prothipendyl hydrochloride
Protirelin
Protriptyline and its salts
Pyrazinamide
Pyridostigmine bromide
Pyrimethamine and its salts
Quinagolide and its salts
Quinapril and its salts and derivatives
Raltitrexed and its salts and derivatives
Ramipril and its salts and derivatives
Ranitidine and its salts (except in solid oral preparations sold in a dosage form containing not more than the equivalent of 75 mg of ranitidine)
Raubasine and its salts
Rauwolfia
Remoxipride and its salts
Rescinnamine and its salts
Reviparin and its salts
Ribavirin
Rifabutin and its salts
Rifampin and its salts and derivatives
Risperidone and its salts
Ritodrine and its salts
Ritonavir

Rocuronium bromide
Ropinirole and its salts
Rosoxacin and its salts
Salmeterol and its salts
Salbutamol and its salts
Salsalate and its salts and derivatives
Saquinavir and its salts and derivatives
Saralasin and its salts
Sargramostim
Selegiline and its salts
Sermorelin and its salts
Sertraline and its salts
Simvastatin
Sodium aurothiomalate
Sodium bromide
Sodium nitroprusside and its salts
Sodium polystyrene sulfonate
Somatrem
Somatostatin
Somatropin
Sotalol and its salts
Spironolactone
Stavudine
Streptozocin
Strontium bromide
Succinimide and its salts and derivatives (except those compounds used for decontaminating water)
Sucralfate
Sulconazole and its salts
Sulfinpyrazone and its salts
Sulindac and its salts
Sulphones and their derivatives
Sumatriptan and its salts
Suprofen and its salts
Suxamethonium chloride
Tacrolimus and its derivatives
Tamoxifen and its salts
Tazobactam and its salts and derivatives
Tazarotene
Temazepam and its salts
Teniposide
Tenoxicam and its salts

Terazosin and its salts
Terbinafine and its salts
Terbutaline and its salts
Terconazole and its salts
Terfenadine and its salts
Terlipressin and its salts
Tetrabenazine and its salts
Thalidomide
Theobromine and its salts
Theophylline and its salts
Thiethylperazine and its salts
Thiocarlide
Thioguanine
Thiopropazate and its salts
Thioproperazine and its salts
Thioridazine and its salts
Thiotepa
Thiothixene and its salts
Thiouracil and its derivatives
Thyroxin and its salts
Tiaprofenic acid and its salts
Ticarcillin and its salts and derivatives
Ticlopidine and its salts
Tilmicosin
Tiludronic acid and its salts
Timolol and its salts
Tinidazole
Tinzaparin and its salts
Tioconazole and its salts (except in preparations for topical and vaginal use)
Tobramycin and its salts and derivatives
Tocainide and its salts
Tolazamide
Tolazoline and its salts
Tolbutamide
Tolmetin and its salts
Topiramate
Topotecan and its salts
Torasemide and its salts
Trandolaprilat and its salts and derivatives
Tranexamic acid
Tranylcypromine
Trazodone and its salts

Treosulfan
Tretamine
Tretinoin (vitamin A acid)
Tretinoin and its salts and derivatives
Triamterene and its salts
Triazolam and its salts
Tricaine and its salts
Trifluoperazine and its salts
Triflupromazine and its salts
Trifluridine
Trihexyphenidyl and its salts
Triiodothyropropionic acid
Trilostane
Trimebutine and its salts
Trimethadione
Trimethaphan camsylate
Trimethoprim and its salts
Trimetrexate and its salts
Trimipramine and its salts
Trioxsalen
Troglitazone
Tropicamide and its salts in preparations for parenteral or ophthalmic use, except when sold for use in diagnostic procedures to an optometrist registered in a province of Canada
L-Tryptophan, when sold as a single ingredient
Tubocurarine chloride
Tybamate
Tylosin and its salts and derivatives, when sold for the treatment of chronic colitis in dogs
Uracil mustard and its salts
Ursodeoxycholic acid and its salts
Valaciclovir and its salts
Valproic acid and its salts
Vancomycin and its salts and derivatives
Vasopressin and its salts
Vecuronium bromide
Venlafaxine and its salts
Verapamil and its salts
Vidarabine
Vigabatrin and its salts and derivatives
Vinblastine and its salts
Vincristine and its salts

Vindesine and its salts
Vinorelbine and its salts
Viomycin and its salts and derivatives
Vitamin A (oral dosage form containing more than 10 000 IU or where daily dosage is more than 10 000 IU)
Vitamin B12 with Intrinsic Factor Concentrate
Vitamin D (oral dosage form containing more than 1000 IU or where daily dosage is more than 1000 IU)
Vitamin K
Xanthinol nicotinate
Xylazine and its salts
Yohimbine and its salts
Zalcitabine and its salts
Zidovudine
Zolpidem and its salts
Zomepirac and its salts
Zopiclone and its salts
Zuclopenthixol and its salts and derivatives

SCHEDULE F - PART II (FDR)

The following is the list of substances referred to in Part II of Schedule F of the *Food and Drug Regulations*.

Acepromazine and its salts
Acetanilide
Adrenocortical hormones and their salts and derivatives, (except hydrocortisone or hydrocortisone acetate, when sold as a single medicinal ingredient in a concentration that provides 0.5% hydrocortisone in preparations for topical use on the skin)
Aminopyrine and its derivatives
Amprolium and its salts
Antipyrine (except preparations for topical use)
Apramycin and its salts
Azithromycin and its salts and derivatives
Centella asiatica extract and active principles thereof
Chlorhexidine and its salts, when used as a topical oral preparation
Chlorothiazide and its salts and derivatives
Chlorpromazine and its salts
Cholestyramine resin
Clarithromycin and its salts and derivatives
Cyclizine
Dihydrostreptomycin and its salts and derivatives
Dirithromycin
Ergot alkaloids and their salts
Erythromycin and its salts and derivatives
Folic acid
Framycetin and its salts and derivatives
Furaltadone and its salts
Furazolidone and its salts
Furosemide
Griseofulvin and its salts and derivatives
Iron derivatives for parenteral use only
Ivermectin, except when sold or recommended for intramuscular injection into horses or for administration to dogs
Kanamycin and its salts and derivatives
Levamisole and its salts
Lincomycin and its salts and derivatives
Liothyronine and its salts
Mebendazole
Meclizine and its salts
Neomycin and its salts and derivatives

Nicarbazin
Nicotine and its salts
Nitrofurantoin and its salts
Novobiocin and its salts and derivatives
Nystatin (except preparations for topical use on the skin) and its salts and derivatives
Oleandomycin and its salts and derivatives
Penicillin and its salts and derivatives, (except amoxicillin, ampicillin, azlocillin, benzathine penicillin, carbenicillin, cloxacillin, dicloxacillin, hetacillin, mecillinam, methicillin, mezlocillin, nafcillin, oxacillin and ticarcillin and their salts and derivatives)
Physostigmine salicylate (except preparations for oral or topical use only)
Polymyxin B and its salts and derivatives, (except for topical use or for local action in the oral cavity or nasal passages)
Praziquantel
Primidone
Promazine and its salts
Reserpine and its salts
Ronidazole and its salts and derivatives
Sex hormones, except the following:
- Androisoxazole
- Androstanolone
- Androstenediol and its derivatives
- Bolandiol and its derivatives
- Bolasterone
- Bolazine
- Boldenone and its derivatives
- Bolenol
- Calusterone
- Clostebol and its derivatives
- Cyproterone and its derivatives
- Diethylstilbestrol and its derivatives
- Drostanolone and its derivatives
- Enestebol
- Epitiostanol
- Ethylestrenol
- Fluoxymesterone
- Formebolone
- Furazabol
- 4-Hydroxy-19-nortestosterone and its derivatives
- Mebolazine
- Megestrol and its derivatives
- Mesabolone
- Mesterolone

Metandienone
Metenolone and its derivatives
Methandriol
Methyltestosterone and its derivatives
Metribolone
Mibolerone
Nandrolone and its derivatives
Norboletone
Norclostebol and its derivatives
Norethandrolone
Oxabolone and its derivatives
Oxandrolone
Oxymesterone
Oxymetholone
Prasterone
Quinbolone
Stanozolol
Stenbolone and its derivatives
Testosterone and its derivatives
Tibolone
Tiomesterone
Trenbolone and its derivatives
Zeranol

Sodium fluoride (in solid oral dosage forms containing more than one milligram of fluoride ion)
Spectinomycin and its salts and derivatives
Spiramycin and its salts and derivatives
Streptomycin and its salts and derivatives
Sulphonamides and their salts and derivatives
Tetracycline and its salts and derivatives (except doxycycline when sold for intramuscular administration in caged birds)
Thiabendazole
Thyroid
Tioconazole and its salts
Trimeprazine and its salts
Tylosin and its salts and derivatives (except when sold for the treatment of chronic colitis in dogs)
Veratrum album and its alkaloids and their salts
Veratrum viride and its alkaloids and their salts
Virginiamycin and its salts and derivatives
Vitamin A
Vitamin D

Vitamin K

SCHEDULE F (FDR)
SYNONYMS

The following is a partial list of substances referred to in Schedule F of the Food and Drug Regulations and their synonyms (may not be all inclusive). The listing is not to duplicate the preceding list in this Section but to provide the synonyms for those substances where other names are commonly used.

ADRENOCORTICAL HORMONES AND THEIR SALTS & DERIVATIVES

Regulatory authority:
FDR Schedule F, Part II.

Note: Examples include adrenocorticoids, corticosteroids (glucocorticoids and mineralocorticoids).

ALKYL NITRITES

Synonyms:
Amyl nitrite, butyl nitrite, isobutyl nitrite.
Regulatory authority:
FDR Schedule F, Part I

CENTELLA ASIATICA extract and its active principles

Synonyms:
Includes hydrocotyle, hydrocotyle asiatica, Indian pennywort, herba centella, Indian water navelwort, marsh penny, white rot, gotu kola.
Regulatory authority:
FDR Schedule F , Part II

DIMETHYLSULFOXIDE

Synonyms:
DMSO, dimethyl sulphoxide, methyl sulphoxide, sulfinylbismethane.
Regulatory authority:
FDR Schedule F, Part I.

LEVOCARNITINE

Schedule F (FDR) - Synonyms

Synonyms :
L-carnitine, carnitine
Regulatory authority :
FDR Schedule F, Part I

SEX HORMONES

Regulatory authority:
FDR Schedule F, Part II

Note: Examples include oestrogens, such as broparestrol, diethylstilbestrol (DES), hydroxyestrone, mestranol, promestriene, quinestrol, etc; and progestogens, such as chlormadinone, desogestrel, dydrogesterone, ethisterone, ethynodiol, gestodene, gestronol, lynoestrenol, medrogestone, norgestrienone, etc; pregneninolone (synonyms: ethisterone, ethinyltestosterone, anhydrohydroxyprogesterone, ethisteronum, praegninum, pregnin); and, progesterone (synonyms: luteohormone, pregnenedione, progesteronum, luteal hormone, luteine, *corpus luteum* hormone).

(This is not an exhaustive list).

Sex hormones which have anabolic activity are excluded from the above listing; these are listed in CDSA Schedule IV.

1.4 Prohibited Substances

1.4.1 Substances prohibited in the *Food and Drug Regulations*

The following is a list of substances prohibited in drug preparations, as specified in the *Food and Drug Regulations*.

Arsenic or any of its salts or derivatives,
Chloroform
Echimidine or any of its salts; or any of the following plant species or extracts or tinctures thereof:

(i) Symphytum asperum,
(ii) Symphytum x uplandicum, or
(iii) any other plant species containing echimidine.

Mercury or a salt or derivative thereof
Methapyrilene or any of its salts,
Methyl salicylate (for internal use in humans).
Nitrous oxide
Oxyphenisatin,
Oxyphenisatin acetate,
Phenacetin in combination with any salt or derivative of salicylic acid,
Phenisatin,
Strychnine or any of its salts, extracts or tinctures of

(i)Strychnos nux vomica
(ii)Strychnos Ignatii, or
(iii)a Strychnos species containing strychnine, other than those species mentioned in (i) and (ii).

PROHIBITED SUBSTANCES (FDR)
SYNONYMS

The following is a list of prohibited substances and their synonyms (may not be all inclusive), and the regulatory authority in the *Food and Drug Regulations*.

ARSENIC (and salts or derivatives of)

Synonyms:
Arsenic acid, *Arsenicum album*, arsine gas, arsenic trioxide, arsenic disulfide.
Regulatory authority:
FDR, section C.01.040

CHLOROFORM

Synonyms:
Chloroformum Anesthesicum, Chloroformum, Chloroformum pro Narcosi, trichloromethane, formyl trichloride.
Regulatory authority:
FDR, section C.01.040

ECHIMIDINE (plant species containing echimidine)

Note : Prickly comfrey (*S.asperum*), russian comfrey (*S.uplandicum*, a non officially recognized name) (*Symphitum x uplandicum*).

Regulatory authority:
FDR, section C.01.038

MERCURY (and salts or derivative of)

Synonyms:
Hydrargyrum, liquid silver, quick silver.
Regulatory authority:
FDR. section C.01.036

METHAPYRILENE (and salts)

Synonyms:
Methapyrilene fumarate, methapyrilene hydrochloride, thenylpyrilene fumarate, thenylpyrilene hydrochloride.
Regulatory authority:
FDR, section C.01.038

METHYL SALICYLATE (for internal use in humans)

Synonyms:
Methyl 2-hydroxybenzoate, wintergreen oil, betula oil, sweet birch oil, teaberry oil, checkerberry oil, gaultheria oil.
Regulatory authority:
FDR, Section C.01.040.1

NITROUS OXIDE

Synonyms:
Dinitrogen monoxide, Dinitrogen oxide, Nitrogen monoxide, Laughing gas, Hyponitrous acid anhydre, Facticious air.
Regulatory authority:
FDR, section C.01.036.1

OXYPHENISATIN

Synonyms:
Dihydroxyphenylisatin, oxyphenisatine.
Regulatory authority:
FDR, section C.01.036

OXYPHENISATIN ACETATE

Synonyms:
Oxyphenisatin diacetate, acetphenolisatin, diacetoxydiphenylisatin, oxyphenisatine acetate.
Regulatory authority:
FDR, section C.01.036

PHENACETIN (in combination with any salt or derivative of salicylic acid)

Synonyms:

Aceto-p-phenetidide, acetophenetidin, acetylphenetidin, paracetophenetidin; phenacetinum, p-Acetophenetidide, p-Acetophenetide, 4'ethoxyacetanilide.
Regulatory authority:
FDR, section C.01.036

PHENISATIN

Synonyms:
Triacetyldiphenolisatin, 1-acetyl-3,3-bis(p-hydroxyphenyl)oxindole diacetate.
Regulatory authority:
FDR, section C.01.036

STRYCHNINE (and salts)

Synonyms:
Strychnos nux vomica, Nux Vomica, Strychnos Ignatii, Ignatia, Ignatius bean.
Regulatory authority:
FDR, section C.01.038

1.4.2 Substances prohibited in the Food and Drug Regulations, and unacceptable in homeopathic preparations at the specified concentrations

Although the substances listed in section 1.4.1 of this document are prohibited in drug preparations, the following substances are accepted in homeopathic preparations, at the given dilution levels :

Arsenic: *Antimonium arsenicicum, a. album, a. bromatum, a. iodatum, a. sulphuratum flavum, a. sulphuratum rubrum, calcarea arsenicica, chininum arsenicicum, chinimum arsenicosum, cuprum arsenicosum, ferrum arsenicicum, kali arsenicosum, natrum arsenicicum*

6X or more (i.e MT, 1X, 2X, 3X, 4X, 5X or its equivalent are unacceptable)

Exception : *Arsenicum metallicum :* 8X or more (i.e MT, 1X, 2X, 3X, 4X, 5X, 6X, 7X or its equivalent are unacceptable)

Mercury: *Aethiops antimonialis, aethiops mercurialis-mineralis, m. aceticus,m. auratus, m. bromatus, m. corrosivius, m. dulcis, m. iodatus flavus, m. iodatus ruber, m. methyenus, m. nitricus, m. praecipitatus albus, m. praecipitatus ruber, m. solubilis, m. sulphocyanatus, m. sulphuratus ruber, m. sulphuricus, m. vivus*

6X or more (i.e MT, 1X, 2X, 3X, 4X, 5X or its equivalent are unacceptable)

Exception : *Mercurius cyanatus :* 8X or more (i.e MT, 1X, 2X, 3X, 4X, 5X, 6X, 7X or its equivalent are unacceptable)

Strychnine: *Strychnimum, s. arsenicicum, s. nitricum, s. phosphoricum, s. sulphuricum*

6X or more (i.e. MT, 1X, 2X, 3X, 4X, 5X or its equivalent are unacceptable)

ignata amara, nux vomica

3X or more (i.e MT, 1X, 2X or its equivalent are unacceptable)

Chloroform: *Chloformum 3X or more (i.e. MT, 1X, 2X or its equivalent are unacceptable)*

Note: Equivalent terms: X or DH
CH or C
CK or K

MT= mother tincture

Mother tincture (starting solution)
Equivalent Dilution Units

1X		
2X	1C	1K
3X		
4X	2C	2K
5X		
6X	3C	3K
7X		
8X	4C	4K

Example: Arsenic 2CH is equivalent to Arsenic 4X. Therefore, the concentration of arsenic is non-compliant.

1.5 Substances, not covered by any of the previous criteria, that have been found to represent an unacceptable potential health risk

The following is a list of substances that have been determined to represent an unacceptable potential health risk.

CALAMUS

Synonyms :
Acorus calamus, Calamus aromaticus, sweet flag root, sweet sedge, sweet root, sweet myrtle, rat root, shuichangpu, kalmus.
Regulatory authority:
FDA, section 9(1)
Health hazard assessment:
Risk of severe liver toxicity.

CANTHARIDES, CANTHARIDIN and their preparations

Regulatory authority :
FDR, section C.01.021

Note: Cantharides, synonym Cantharis, is acceptable in homeopathic preparations at concentration equal to or lower than 3X.

Cantharidinum, synonym Cantharidin, is acceptable in homeopathic preparations at concentration equal to or lower than 8X.

CEDAR OIL :

Regulatory authority :
FDR, section C.01.021

CHAPARRAL

Synonyms:
Lareus tridentata, Larrea divaricata, creosote bush, greasewood, hediondilla.
Regulatory authority:
FDA, section 9(1)

Health hazard assessment:
Risk of severe liver toxicity in human. Nephrotoxicity was obseved in animal as well.

Note : *Larrea divaricata* is acceptable in homeopathic preparations at concentration equal to or lower than 1X

CROTON OIL

Regulatory authority :
FDR, section C.01.021

GERMANDER

Synonyms:
Teucrium genus, *Teucrium chamaedrys* (wall germander), *Teucrium scordium* (water germander), *Teucrium scorodonia* (sage-leaved germander, wood sage, garlic sage), *Teucrium marum*.
Regulatory authority:
FDA, section 9(1)
Health hazard assessment:
Risk of severe liver toxicity.

Note : *Teucrium scorodonia* and *Teucrium marum* are acceptable in homeopathic preparations at concentration equal to or lower than 1x.

1.6 Mineral and Vitamin supplements
1.6.1 Mineral supplements

The following list of mineral supplements are those substances specifically mentioned in Category *IV* Monograph and in the *Labelling Standard for Mineral Supplements.*

All minerals in dosage form are considered to be drugs (no claim required).

These minerals, at the daily dosages indicated **(see following page)**, are the only ones considered as coming under the definition of mineral supplements for "products subject to special measures".

CALCIUM
CHLORIDE
CHROMIUM
COBALT
COPPER
FLUORINE
IODINE
IRON
MAGNESIUM
MANGANESE
MOLYBDENUM
NICKEL
PHOSPHORUS
POTASSIUM
SELENIUM
SILICON
SODIUM
SULPHUR
TIN
VANADIUM
ZINC

MINIMUM AND MAXIMUM DAILY DOSAGES

Element	Unit	Minimum Dosage	Maximum Dosage
Calcium	mg	125	1500
Chloride	mg	0	1000
Chromium	mcg	0	500
Cobalt	mcg	0	44
Copper	mg	1	5
Fluorine	mg	0.25	1
Iodine	mg	0.05	0.5
Iron	mg	4	35
Magnesium	mg	50	500
Manganese	mg	0	30
Molybdenum	mcg	0	50
Nickel	mcg	0	5
Phosphorus	mg	125	1000
Potassium	mg	0	780
Selenium	mcg	0	200
Silicon	mg	0	20
Sodium	mg	0	100
Sulphur	mg	0	30
Tin	mg	0	20
Vanadium	mcg	0	75
Zinc	mg	0	50

MINERAL SUPPLEMENTS : ACCEPTABLE SOURCES

This section lists the mineral supplements and acceptable sources.

CALCIUM

Acceptable sources :
Calcium chloride, calcium citrate, calcium lactate, calcium phosphate dibasic, dolomite, calcium glycerophosphate, calcium glubionate, calcium gluconate, calcium phosphate tribasic, calcium HVP/HAP chelate, calcium carbonate, oyster shells, calcium sulphate, bone meal
Regulatory authority:
FDR, section D.05.007

CHLORIDE

Acceptable sources :
Sodium chloride, potassium chloride
Regulatory authority :
FDR, section D.05.006

CHROMIUM

Acceptable sources :
Chromium chloride, chromium citrate, chromium succinate, chromium fumarate, chromium glutarate, chromium malate, yeast, chromium HVP/HAP chelate
Regulatory authority :
FDR, section D.05.006

COBALT

Acceptable sources :
Cyanocobalamin
Regulatory authority :
FDR, section D.05.006

COPPER

Acceptable sources :

Cupric sulfate, copper HVP/HAP chelate, cupric gluconate, cupric carbonate, cupric citrate, cupric fumarate, cupric glutarate, cupric malate, cupric succinate
Regulatory authority:
FDR, section D.05.007

FLUORINE

Acceptable sources :
Sodium fluoride, potassium fluoride
Regulatory authority:
FDR, sections D.05.007 and D.05.008

IODINE

Acceptable sources :
Potassium iodide, sodium iodide, kelp
Regulatory authority:
FDR, section D.05.007

IRON

Acceptable sources :
Reduced iron, iron citrate, iron dextran complex, iron polysaccharide, ferric glycerophosphate, ferric citrate, ferric ammonium citrate, ferrous carbonate, ferrous fumarate, ferrous gluconate, ferrous glutarate, ferrous malate, ferrous succinate, ferrous sulfate, iron HPV/HAP chelate
Regulatory authority:
FDR, sections D.05.007 and C.01.030

MAGNESIUM

Acceptable sources :
Magnesium fumarate, magnesium gluconate, magnesium carbonate, magnesium glutarate, magnesium malate, magnesium succinate, magnesium chloride, magnesium oxide, magnesium citrate, magnesium ascorbate, magnesium HVP/HAP chelate, magnesium sulfate, magnesium glycerophosphate, magnesium acetate, magnesium lactate, magnesium hydroxide
Regulatory authority:
FDR, section D.05.007

MANGANESE

Acceptable sources :
Manganese citrate, manganese glycerophosphate, manganese gluconate, manganese sulfate, manganese HVP/HAP chelate
Regulatory authority :
FDR, section D.05.006

MOLYBDENUM

Acceptable sources :
Molybdenum citrate, molybdenum glutarate, molybdenum malate, molybdenum fumarate, molybdenum succinate, sodium molybdate, molybdenum HVP chelate.
Regulatory authority :
FDR, section D.05.006

NICKEL

Acceptable sources :
Nickel sulphate
Regulatory authority :
FDR, section D.05.006

PHOSPHORUS

Acceptable sources :
Phosphorus HVP/HAP chelate, calcium phosphate monobasic/dibasic/tribasic, potassium phosphate (monobasic/dibasic), sodium phosphate, calcium phosphate
Regulatory authority:
FDR, section D.05.006

POTASSIUM

Acceptable sources :
Potassium gluconate, potassium chloride, potassium citrate, potassium acetate, potassium bicarbonate, potassium gluconate, potassium glycerophosphate
Regulatory authority :
FDR, section D.05.006

SELENIUM

Acceptable sources :
Selenium HVP/HAP chelate, selenium yeast, sodium selenite

Mineral supplements - Acceptable sources

Regulatory authority :
FDR, section D.05.006

SILICON

Acceptable sources :
Sodium metasilicate, silicon dioxide, silicon HVP/HAP chelate, horsetail
Regulatory authority :
FDR, section D.05.006

Note : Horsetail : Equisetum arvense L.species only. Data (or certification) must be submitted to show that thiaminase has been inactivated

SODIUM

Acceptable sources :
Sodium bicarbonate, sodium chloride
Regulatory authority :
FDR, section D.05.006

SULPHUR

Acceptable sources :
Calcium sulphate, cupric sulfate, ferrous sulfate, manganese sulfate, magnesium sulfate, zinc sulfate, nickel sulfate.
Regulatory authority :
FDR, section D.05.006

TIN
Acceptable sources :
Stannous chloride
Regulatory authority :
FDR, section D.05.006

VANADIUM

Acceptable sources :
Vanadium HVP/HAP chelate, vanadium citrate, sodium metavanadate
Regulatory authority :
FDR, section D.05.006

Mineral supplements - Acceptable sources

ZINC

Acceptable sources :
Zinc chloride, zinc citrate, zinc fumarate, zinc gluconate, zinc glutarate, zinc malate, zinc succinate, zinc sulphate, zinc HV/HAP chelate
Regulatory authority :
FDR, section D.05.006

Additional information

Additional information to assist in determining if a Mineral is considered a drug and if it is subject to special measures.

Mineral Supplement: meets criteria of Category (Cat) IV Monograph or Labelling Standard (LS), with or without therapeutic claim, is a drug, and is subject to special measures.

Mineral supplement meets dosages and not sources as Cat IV Monograph or LS: with or without therapeutic claim, is a drug but not subject to special measures.

Product containing Mineral less than the minimum doses and does not meet sources Cat IV Monograph or LS: no therapeutic claim, is a drug non conform to the Drug Regulations and is not subject to special measures.
Products containing Mineral less than the minimum dose and does not meet sources as Cat IV Monograph or LS: with therapeutic claim, not a Mineral supplement, but is a drug, not subject to special measures.

Product containing Mineral more than the maximum doses and does not meet sources as Cat IV Monograph or LS: no therapeutic claim, not a Mineral supplement, but is a drug, not subject to special measures. Could be considered a new drug.
Products containing Mineral more than the maximum dose and does not meet sources as Cat IV Monograph or LS: with therapeutic claim, not a Mineral supplement, but is a drug, not subject to special measures. Could be considered a new drug.

Mineral supplement + herb as NON Medicinal Ingredient: meets Cat IV Monograph and LS, with or without therapeutic claim is a drug, and is subject to special measures.

Product containing Mineral + herb as ingredients, and less than the minimum dosages in Cat IV Monograph or LS: no therapeutic claim, is a drug non conform to the Drug Regulations and is not subject to special measures. With therapeutic claim, is a drug but not subject to special measures.

Mineral supplement + herb as active ingredient: meets dosages and sources as Cat IV Monograph or LS, with or without therapeutic claim, is a drug but not subject to special measures.

Please note that Minerals may also be present in cosmetics and foods.

1.6.2 Vitamin Supplements

The following list of vitamin supplements are those substances specifically mentioned in Category *IV Monograph* and in the *Labelling Standard for Vitamin Supplements*.

All vitamins in dosage form are considered to be drugs (no claim required).

These vitamins, at the daily dosages indicated are the only ones considered as coming under the definition of vitamin supplements for "products subject to special measures"

BIOTIN
D-PANTOTHENIC ACID
FOLIC ACID
NIACIN
NIACINAMIDE
VITAMIN A
VITAMIN B_1
VITAMIN B_2
VITAMIN B_6
VITAMIN B_{12}
VITAMIN C
VITAMIN D
VITAMIN E

MINIMUM AND MAXIMUM DAILY DOSAGES

Vitamin	Minimum under 6 years	Minimum over 6 years	Maximum all ages
vitamin A	1000 IU	1600 IU	10 000 IU
vitamin B_1	0.4 mg	0.6 mg	100 mg
vitamin B_2	0.6 mg	1.0 mg	100 mg
niacin and/or niacinamide	4.0 mg	6.0 mg	500 mg
vitamin B_6	0.6 mg	1.0 mg	250 mg
pantothenic acid	3.0 mg	5.0 mg	500 mg
folic acid	0.05 mg	0.05 mg	1 mg
biotin	-	-	500 mcg
vitamin B_{12}	2 mcg	2 mcg	1000 mcg
vitamin C	20 mg	20 mg	1500 mg
vitamin D	200 IU	200 IU	1000 IU
vitamin E	5 IU	10 IU	1000 IU

Vitamin Supplements : Synonyms / Acceptable Sources

The following is a partial list of vitamin supplements, synonyms (may not be all inclusive) and acceptable sources.

D-PANTOTHENIC ACID

Synonyms:
Pantothenic acid
Acceptable source :
Calcium pantothenate, d-calcium pantothenate
Regulatory authority:
FDR, sections D.04.009 and D.04.010

NIACIN

Synonyms:
Nicotinic acid
Regulatory authority:
FDR, sections D.04.009 and D.04.010

NIACINAMIDE

Synonyms:
Nicotinamide
Regulatory authority:
FDR, sections D.04.009 and D.04.010

VITAMIN A

Acceptable source :
Vitamin A acetate, vitamin A palmitate
Regulatory authority :
FDR, section D.04.009 and D.04.010

Note : Beta carotene is metabolized to vitamin A in the body; it is a source of vitamin A or provitamin A

VITAMIN B1

Synonyms:

Thiamine, thiamine hydrochloride
Regulatory authority:
FDR, sections D.04.009 and D.04.010

VITAMIN B_2

Synonyms:
Riboflavin
Acceptable source :
Riboflavin-5-phosphate
Regulatory authority:
FDR, sections D.04.009 and D.04.010

VITAMIN B_6

Synonyms:
Pyridoxine, pyridoxine hydrochloride
Acceptable source :
Pyridoxal-5-phosphate, pyridoxal hydrochloride
Regulatory authority:
FDR, sections D.04.009 and D.04.010

VITAMIN B_{12}

Synonyms:
Cyanocobalamin, dibencozide(*)
Regulatory authority:
FDR, sections D.04.009 and D.04.010
(*) **Unacceptable synonym**

VITAMIN C

Synonyms:
Ascorbic acid
Acceptable source :
Calcium ascorbate, sodium ascorbate
Regulatory authority:
FDR, sections D.04.009 and D.04.010

VITAMIN D

Synonyms:

Vitamin D_2, vitamin D3, alfacalcidol(*), calcifediol(*), calcitriol(*), cholecalciferol(*), colecalciferol(*), dihydrotachysterol(*), ergocalciferol(*), viosterol(*)
Regulatory authority:
FDR, sections D.04.009 and D.04.010
(*) Unacceptable synonyms

VITAMIN E

Synonyms :
Alpha tocopherol(*), beta tocopherol(*), delta tocopherol(*), gamma tocopherol(*), alpha tocotrienol(*)
Acceptable source :
d & dl alpha tocopheryl acetate, d & dl alpha tocopheryl acid succinate
Regulatory authority:
FDR, sections D.04.009 and D.04.010.
(*) Unacceptable synonyms

Additional information

Additional information to assist in determining if a Vitamin is considered a drug and if it is subject to special measures.

Vitamin supplement: meets criteria of Category (Cat) IV Monograph or Labelling Standard (LS), with or without therapeutic claim, is a drug, and is subject to special measures.

Vitamin supplement meets dosages and not sources as Cat IV Monograph or LS: with or without therapeutic claim, is a drug but not subject to special measures.

Product containing Vitamin less than the minimum doses and does not meet sources as Cat IV Monograph or LS: no therapeutic claim, is a drug not conform to the Drug Regulations and is not subject to special measures.
Products containing Vitamin less than the minimum dose and does not meet sources as Cat IV Monograph or LS: with therapeutic claim, not a Vitamin supplement, but is a drug, not subject to special measures.

Product containing Vitamin more than the maximum doses and does not meet sources as Cat IV Monograph or LS: no therapeutic claim, not a Vitamin supplement, but is a drug, not subject to special measures. Could be considered a new drug.
Product containing Vitamin more than the maximum dose and does not meet sources as Cat IV Monograph or LS: with therapeutic claim, not a Vitamin supplement, but is a drug, not subject to special measures. Could be considered a new drug.

Vitamin supplement + herb as NON Medicinal Ingredient: meets Cat IV Monograph and LS, with or without therapeutic claim is a drug and is subject to special measures.

Product containing Vitamin + herb as ingredients, and less than the minimum dosages in Cat IV Monograph or LS: no therapeutic claim, is a drug not conform to the Drug Regulations, and is not subject to special measures. With therapeutic claim, is a drug but not subject to special measures.

Vitamin supplement + herb as active ingredient: meets dosages and sources as Cat IV Monograph or LS, with or without therapeutic claim, is a drug but not subject to special measures.

Please note that Vitamins may also be present in cosmetics and foods.

Section 2. Products not Subject to Special Measures (PNSSM)
2.1 Substances considered a drug

The list in section 2 relates to **products not subject to special measures**. It covers substances considered a drug, regardless of the type of representation made regarding the use of a product. These substances are intended for internal use, unless otherwise indicated.

This list (section 2) is intended to identify substances considered to be a drug as defined by the Food and Drugs Act. It is important to note that the Act establishes what a drug "includes", but not what a drug "is". It also distinguishes drugs on the basic of the purpose for which the substance is manufactured, sold or represented. The major factors used in determining whether a product is to be considered a drug are: the pharmacological activity of the ingredients; the purpose for which the product is intended; and the representations made regarding its use, including directions for use. Other factors, such as precise dosage form, design features of a product (e.g. a patch delivery system which is intended as a drug by design), may be considered in the determination of a product status. For example, a product containing a substance with known pharmacological activity such as acetaminophen, will be considered a drug even in the absence of a medicinal claim. Conversely, a product represented for medicinal purposes would be considered a drug, requiring the safety and efficacy of the active substances be established. Both these products would require a valid DIN.

It is not the intent to include in section 2, a comprehensive listing of information pertaining to the three major factors used in determining the drug status of a product. This section will be limited to a few substances that have been found in products considered to be drugs in the Canadian marketplace, and for which the safety and efficacy have not been established.

AMINO ACIDS (Single or in mixture outside of a naturally occurring protein configuration) :

Arginine
lysine
phenylalanine
tryptophan
tyrosine

Rationale:
Effect of long-term administration has not been established.
Regulatory authority:

FDR, section C.08.002

Note: Dietary protein is made up of combinations of 18-20 single amino acids in various proportions. Amino acids in protein configuration are acceptable as nonmedicinal ingredients (no claims may be inferred for them).

MELATONIN :

Synonyms:
Pineal gland extract, N-[2-(5-Methoxy-IH-indol-3-yl)ethyl]acetamide, N-acetyl-5-methoxytrytamine.
Rationale:
Melatonin is a hormone in which the effects of long term administration have not been studied.
Regulatory authority:
FDR, section C.08.002

ORNITHINE :

Rationale:
Effect of long-term administration has not been established.
Regulatory authority :
FDR, section C.08.002

Note : Ornithine is not a component of food protein, there is no other legitimate use for this substance, except as a drug.

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Health Canada / Santé Canada

Therapeutic Products Programme /
Programme des produits
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OTTAWA (Ontario)
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To: Associations

I am pleased to inform you that an updated version of the Therapeutic Products Compliance Guide is available on our Website. The address is www.hc-sc.gc.ca/ hpb-dgps/ therapeut.

The main changes to the English and French versions are corrections to Schedule F of the *Food and Drugs Regulations*, additions to Schedule III of the *Controlled Drug and Substance Act*, deletion to Schedule IV of the *Controlled Drug and Substance Act*, additions of acceptable sources for Sulphur, additional information concerning Chaparral and a modification to Echemidine.

Aux : Associations

Je suis heureux de vous informer qu'une nouvelle version du Guide de conformité des produits thérapeutiques est maintenant disponible sur notre site Web à l'adresse suivante: www.hc-sc.gc.ca /hpb-dgps/therapeut.

Les principaux changements à la version française et anglaise sont des corrections à l'annexe F du *Règlement sur les aliments et drogues*, des ajouts à l'annexe III de la *Loi* réglementant certaines drogues et autres substances, un retrait à l'annexe IV de la Loi réglementant certaines drogues et autres substances, l'ajout de sources acceptables pour le souffre, une précision sous Chaparral et une modifi-

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cation sous Echemidine.

For more information please contact the Therapeutic Products Programme Regional Office nearest to you. A list of these office telephone numbers are attached.

Pour plus de renseignements, veuillez communiquer avec le bureau régional du Programme des produits thérapeutiques le plus près. Vous trouverez ci-dessous, une liste des numéros de téléphone.

Atlantic Region (St. John's) / Région de l'Atlantique (St. John)
(709) 772-2125

Quebec Region / Région du Québec (Montréal)
(514) 646-1353
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Ontario Region (Toronto) / Région de l'Ontario
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Central Region (Winnipeg) / Région du Centre
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Director General / Directeur général